Anthony J. Costantini John Dellaportas Brian Damiano 1540 Broadway New York, New York 10036 (212) 692-1000 Attorneys for Plaintiff Drew Scientific, Inc.

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

DREW SCIENTIFIC, INC.,

Plaintiff,

POINTCARE TECHNOLOGIES, INC.,

Defendant.

COMPLAINT

Drew Scientific, Inc. ("Drew"), by and through its attorneys Duane Morris for its Complaint against defendant PointCare Technologies, Inc. ("PointCare") alleges the following:

- Drew is a company organized and existing under the laws of the State of Texas. Its principal place of business is located at 4230 Shilling Way, Dallas, Texas.
- PointCare is a company organized and existing under the laws of the 2. Commonwealth of Massachusetts. Its principal place of business is located at 181 Cedar Hill Street, Marlborough, Massachusetts.
- There is a complete diversity of citizenship between the parties hereto and 3. the amount in controversy far exceeds the jurisdictional amount of \$75,000. There is thus subject matter jurisdiction under 28 U.S.C. § 1332.

- 4. Both parties conduct business activities within this District and in a Manufacturing, Distribution and Co-Marketing Agreement dated June 2006 (the "Agreement"), they have agreed, among other things, that "[A]ny legal action filed pursuant to and/or related to this Agreement or its interpretation shall be filed in the U.S. District Court for the Southern District of New York." The parties have thus agreed that this Court has personal jurisdiction over them, and the venue of this action in this District is proper pursuant to 28 U.S.C. § 1391.
- 5. The primary purpose of this action is to permanently enjoin the defendant from distributing or attempting to distribute certain equipment in the United States and any other territories assigned to Drew or otherwise violating the Agreement, to obtain the return of certain equipment to Drew, to otherwise compel compliance with the Agreement, and to recover damages for any violations of the Agreement that have occurred to date. A complete copy of the Agreement and its accompanying Annexes is attached hereto as Exhibit 1.

FACTUAL BACKGROUND

6. The Agreement was entered into in June 2006, and it combined the efforts of the parties in two significant and related respects. In the first respect, Drew agreed to modify its Excell 22 TM hematology platform to accommodate PointCare's proprietary CD4 Lymphocyte Assay, CD4 sure. TM The integrated device (also referred to as the high throughput ("HT") platform), which was to be developed primarily at Drew's expense, is to be used to measure CD4 Lymphocyte levels in patients infected with HIV. CD4 lymphocyte levels are indicative of the success or lack thereof of current treatment.

- By the terms of the Agreement, development of the HT platform was 7. to be a joint effort, with Drew and PointCare each having allocated responsibilities (e.g., PointCare being responsible for assuring that the CD4 assay is compatible with the Drew HT instrumentation). Two different versions of the integrated HT platform device are to be marketed and sold by the respective parties in assigned territories. To date, Drew has invested more than \$1,000,000 in this development collaboration and afforded PointCare personnel complete access to Drew's confidential, proprietary technological information and know-how relative to the Excell 22TM platform. Drew has also shared its confidential marketing plans and sales strategies with PointCare. Under the terms of the Agreement, PointCare is prohibited from using this information without Drew's consent, even if the Agreement should be terminated. In the event the Agreement is terminated, however, PointCare may develop and distribute its own HT platform. Furthermore, Drew's distribution rights to the NP system discussed below are contingent upon its successful development and marketing of the HT system. As discussed further below, PointCare has intentionally acted in bad faith to frustrate Drew's ability to complete the HT platform project and has used this conduct to improperly refuse to recognize Drew's rights relative to the Near Patient system.
- 8. The second significant aspect concerns PointCare's Near Patient ("NP") platform, which permits the same type of HIV patient testing to be performed locally, i.e., in a non-hospital environment. PointCare agreed to enter into a third party Development and Manufacturing Agreement to manufacture this device, which would then be purchased by PointCare, and privately labeled and sold to Drew, which

was granted certain distribution rights to the NP platform, including the right to be the entity primarily responsible for the marketing and sales of the NP platform in the United States, the United Kingdom, Europe and much of Asia. Drew has already expended more than \$50,000 to date relative to marketing the NP platform, has lined up potential customers, and PointCare has been provided with unfettered access to Drew's marketing plans for its territories. There is a significant technological overlap between the HT and NP devices, and to some extent, they are competitive. For this reason, the Agreement allocates territories to the parties and the party designated for a specific territory is primarily responsible for the marketing and sale of both systems in that assigned territory.

Document 1

- On information and belief, PointCare has recently received approval by 9. the Food and Drug Administration ("FDA") for the NP platform, using Drew's hematology system to produce the hematology data relied upon in its FDA submission. PointCare's conduct to date has contributed significantly to the delays experienced with respect to the HT program and PointCare has intentionally and in bad faith stymied Drew's efforts to finalize the HT platform for FDA submission by asserting conditions precedent to the performance of its obligations which are not included in the Agreement between the parties.
- Of the two platforms (HT and NP), development of the HT platform is the 10. more challenging due to its complexity, requiring substantial input and cooperative efforts by the research and development teams of both PointCare and Drew. These teams did not always agree on how to address critical technical, development and design issues. The time that it took for the teams to reach consensus, as well as technical challenges

Escalon's President and CEO conducted an investigation and furnished a 11. detailed reply on October 3, 2007. No substantive response was received from PointCare until October 26, when PointCare asked, for the first time, that the Agreement be modified in ways that were significantly advantageous to PointCare and detrimental to Drew. Specifically, PointCare sought to reverse the original transaction by reallocating

marketing responsibilities for key territories, with the net effect potentially of creating competition between Drew's and PointCare's marketing of the two devices.

- Prior to that response, PointCare's President complained that Drew's 12. distributor in Russia, a territory assigned to Drew under the Agreement, was missing out on an NP tender by Russian authorities. Drew's distributor denied that such a tender was taking place. Drew then requested from PointCare specific information about the purported tender and an appropriate certification of the NP technology (without which a response to the purported tender could not be made).
- Significantly, PointCare's President did not respond to these requests. 13. Escalon's President called on October 18 to discuss the relationship between the parties and to reiterate the requests. This call was not returned by PointCare's President, who sent the October 26 e-mail (about proposed contract modifications) instead.
- At about the same time (Fall, 2007), PointCare was, upon information and 14. belief, experiencing financial distress and was looking for new investors or ways to gain additional capital. In this regard, Drew received reports that at least one distributor was approached by PointCare executives at the AACC convention about the potential to secure marketing rights from PointCare relative to the NP Product in geographic territories assigned to Drew under the Agreement. In addition, PointCare reportedly sought to market the NP product to an entity within Drew's United States territory with a view toward transshipments to PointCare territories - - an intentional, bad faith attempt to circumvent Drew's rights under the Agreement and to market said rights for its own financial gain. Such approaches would make no sense unless PointCare was planning to disavow the Agreement.

- Agreement by refusing to return an NP device to Drew that Drew had sent to PointCare, at its request, so that PointCare could perform a software modification. The device was located at Drew's Dallas headquarters and was being used by Drew to train its personnel so that they would be able to effectively market the NP device upon FDA approval. When PointCare requested return of the machine for a software upgrade, it promised to re-deliver the instrument to Drew by November 2, before the next round of training was scheduled to begin. Instead, Drew was informed on November 1 that at the direction of PointCare's President, the NP device would not be returned to Drew. Repeated requests for the return of the NP instrument have been rebuffed, in violation of both the explicit and implicit cooperation provisions of the Agreement.
- 16. When an explanation for this aberrant behavior was sought, PointCare's President sent an e-mail unilaterally declaring the Agreement "null and void" and suspending all PointCare participation in fulfilling the Agreement until after a meeting on her contractual modification demands. This conduct violates the Agreement in several respects.
- 17. In response, an e-mail was sent on November 7, requesting a clarification of the "null and void" letter. At a November 8 meeting, PointCare's President demanded a proposed modification to the Agreement, saying that PointCare would formally terminate the Agreement if Drew was unwilling to modify the Agreement by unilaterally abandoning its potentially most lucrative territories in favor of PointCare. These assertions served to confirm to Drew its suspicions that PointCare was intentionally and

wrongfully taking measures aimed at taking away Drew's lawful rights so that PointCare could then re-market such rights to others to alleviate its own financial pressures.

- 18. Later that same day, Drew rejected the proposed modification and asked for the notice of material breach required under Section 6.9 of the Agreement, with as much specificity as possible so that it could determine (i) whether there was a breach and (ii) if so, whether it could be cured within the sixty days allocated under the Agreement. Drew also asked that PointCare immediately return the NP device to Drew so that the device could be used for demonstration at a then-upcoming international conference. Because of the immediacy of the situation, Drew requested that PointCare respond by Friday, November 9.
- 19. The next day, PointCare purported to give the requisite Default Notice, claiming Drew's supposed failure to comply with the HT development schedule in the Agreement (which had been modified several times) as a material breach. The Notice did not address the return of the NP device. Subsequent attempts by Drew to get a substantive response from PointCare as to this latter issue received various "explanations", the most recent of which is that the device would not be returned until the HT platforms were marketable.
- 20. On the same day that PointCare acknowledged that the Agreement was still operative, it unilaterally removed references to Drew on its website. PointCare's refusal to cooperate and to perform its obligations relative to the HT program continued and continue to date.
- 21. Under the Notice, Drew had sixty days to correct any default. Although Drew does not believe it is in default under the Agreement, it nonetheless took all steps

that it could take to expedite its part in the finalization of the project. On December 7, 2007, Drew notified PointCare that it had developed the HT platform to the point where PointCare had to perform its obligations and determine whether its assay and the HT platform would interface and operate together effectively. Drew further noted that an independent expert that had previously been endorsed by PointCare's technical team, Dr. Chow, had been present while Drew tested the instrument, that he had verified its performance and that Drew was ready to ship the HT instrument to PointCare for delivery during the week of December 10, 2007, well within the sixty-day "cure" period allegedly triggered by the Default Notice provided by PointCare.

- Since that time, Drew has made several attempts to arrange for (i) the shipment of the HT device to PointCare; (ii) PointCare's access to the data relied upon by the expert, Dr. Chow; and (iii) consultation between PointCare and Dr. Chow with respect to his report. On each occasion, PointCare has refused to take delivery on several pretenses and has refused to even speak with Dr. Chow, in effect leaving Drew in a position where it is unable to "cure" any alleged default and move forward with its FDA submission for the HT platform.
- One of the false pretenses asserted by PointCare relates to its demand for underlying test data. Even though Drew is under no obligation to provide such confidential information, Drew did provide PointCare with Dr. Chow's test report, which clearly showed the data that he relied upon when stating the instrument was ready to be shipped to PointCare, and even offered direct access to Dr. Chow to discuss his findings.
- 24. Despite receipt of the Chow report and Drew's offer to set up a teleconference with Dr. Chow, PointCare continued to refuse delivery of the HT

platform, falsely claiming, among other things, that Dr. Chow's report noted device failures and that Drew had not performed needed accuracy tests. Moreover, PointCare even went so far as to bemoan the lack of testing that was PointCare's responsibility under the Agreement (and the very reason the device was being shipped to them.)

Finally, PointCare insisted, prior to any delivery, on Drew providing additional confidential data; data that is utterly unnecessary for and has no relation to the testing that PointCare is contractually obligated to conduct. At the same time, PointCare advised Drew that the Agreement between the parties was terminated for failure to cure a material breach—timely development of the HT platform.

As mentioned above, Drew has also attempted on several occasions to secure the return of its NP device from PointCare. PointCare has steadfastly refused to return the device on the stated premise that the device can only be used to support Drew's marketing efforts and that those marketing efforts can only be pursued when the HT platform receives FDA approval. PointCare's recalcitrance has created the perfect Catch-22 situation, i.e., since PointCare won't accept HT delivery and conduct tests of compatibility, Drew cannot complete the HT platform development and establish that the HT device meets specifications. Therefore and due to no fault on its part, Drew's ability to complete its FDA submission and fulfill its contractual obligation relative to the HT platform is frustrated. As a consequence of PointCare's own actions, PointCare then asserts that Drew is in breach, refuses to cooperate, thus risking the entire HT program, as well as Drew's substantial investment in it and also refuses to return the NP device to Drew or allow it to begin selling the NP devices in its territories.

- Upon information and belief, PointCare has received FDA approval of the NP device, after submitting data generated using one of Drew's machines. Since Drew has the primary responsibility for marketing the NP device in the United States, this means that Drew could commence marketing and selling the device in the United States where it has many potential customers once the HT device meets specifications. By refusing to accept delivery of the HT device and fulfilling its obligations, PointCare is effectively preventing Drew from securing FDA approval to market its HT instrument and from successfully selling the NP device in its assigned territories, including the United States, as the parties agreed.
- Upon information and belief, Drew asserts that PointCare's true underlying motive is to reclaim primary sales and marketing rights for territories which contractually belong to Drew by mutual agreement of the parties, including but not limited to the United States, Russia, the European Union, and much of Asia. Such bad faith conduct has and will continue to deprive Drew of the marketing rights that were mutually agreed upon and bargained for and will irreparably harm Drew's reputation within the medical device distribution community. (Drew has exhibited a prototype of the NP platform at trade shows on several occasions and, via its efforts, generated a good deal of interest).
- 28. Moreover, the intentional blocking of Drew's HT product development by PointCare and any effort by PointCare to develop an alternative HT platform with another manufacturer, especially if it shares Drew's technologies and know-how with a third party for such a purpose, will also cause Drew irreparable harm. Drew, which has expended more than \$ 1 million on this project to date, will have to find a suitable

replacement for the CD4 assay, redesign the HT machine so that it is compatible with the new assay, and then catch-up to the marketing lead that PointCare is attempting to create for itself. Additionally, any loss of its intellectual property would significantly and irreparably damage Drew.

- Since, upon information and belief, PointCare does not have the expertise 29. necessary to manufacture the HT, Drew has bona fide concerns that PointCare may provide Drew's proprietary information to PointCare's putative manufacturer, thus irreparably harming Drew and directly violating the terms and conditions of the Agreement.
- As to the distribution with respect to both products, Drew is concerned, 30. based upon information and belief, that PointCare has and intends to continue to approach distributors in territories assigned to Drew under the Agreement to solicit their interest in licensing such rights from PointCare, undermining Drew's efforts, causing confusion in the distribution channel and damaging Drew's image and reputation among its distributors and customers. Whether these are presently Drew distributors or competitors of Drew distributors, Drew's distributor relationships will be severely harmed and distributors and customers will certainly come to the negative and inaccurate impression that Drew's important joint venture with PointCare has failed and that the failure is Drew's fault. If PointCare is successful in enticing any Drew distributor to market the NP system, it will also have the effect of putting that distributor in violation of its distribution agreement with Drew because of the competitive overlap mentioned previously. On a larger scale, Drew will be deprived of territories awarded to it under the

Agreement as a trade-off for the considerable investment Drew has made to develop the integrated HT technology and to market both products.

FIRST CAUSE OF ACTION BREACH OF CONTRACT- DAMAGES

- 31. Drew repeats and realleges paragraphs 1 30 above.
- 32. The Agreement is a valid contract entered into by Drew and PointCare.
- 33. Drew has fully performed its obligations under the Agreement and remains ready, willing and able to continue to perform its obligations under the Agreement.
- ommunicating defamatory information to Drew's distributors, by disclosing Drew's highly confidential technological information and marketing plans that the Agreement specifically obligates PointCare to protect, and by otherwise: 1) failing to live up to its responsibilities under the Agreement such as taking delivery of the HT system and conducting tests it is contractually responsible to perform; 2) wrongfully terminating the Agreement in bad faith with the intent of wrongful gain; 3) wrongfully refusing to cooperate with Drew to complete the HT development; 4) improperly soliciting distributors to license distribution rights from PointCare that are the lawful property of Drew under the Agreement; 5) wrongfully refusing to return the NP machine to Drew and support its efforts to market and sell the NP within the Drew territories; 6) knowingly violating Drew's intellectual property rights; 7) knowingly violating its non-disclosure obligations to Drew, and 8) acting in bad faith to intentionally delay or destroy Drew's HT platform development program.

Drew to suffer irreparable injuries, as well as substantial monetary damages. Drew also faces the total loss of the substantial investment it has made in both the HT and NT platforms. On information and belief, the amount of monetary damages well exceeds \$1,000,000.

SECOND CAUSE OF ACTION

BREACH OF CONTRACT - PERMANENT INJUNCTION

- 36. Drew repeats and realleges paragraphs 1 35 above.
- 37. The Agreement is a valid contract entered into by Drew and PointCare.
- 38. Drew has fully performed its obligations under the Agreement and remains ready, willing and able to continue to perform its obligations under the Agreement.
- 39. PointCare has materially breached the Agreement by, *inter alia*, communicating defamatory information to Drew's distributors and by disclosing Drew's highly confidential technological information and marketing plans that the Agreement specifically obligates PointCare to protect. It is also on the verge of damaging Drew's relationships with its distributors by offering products competitive to Drew's and it is severely hampering Drew's development of the HT system by its unwarranted refusal to conduct compatibility tests. As a result, Drew is threatened with substantial and irreparable harm that cannot be compensated by money damages alone.
- 40. PointCare should be permanently enjoined from violating its Agreement with Drew and communicating with distributors for territories assigned to Drew under the Agreement, with respect to either the HT or NP platforms.

THIRD CAUSE OF ACTION

DECLARATORY JUDGMENT

- 41. Drew repeats and realleges paragraphs 1 40 above.
- 42. An actual controversy exists between Drew and PointCare regarding PointCare's misconduct and purported termination of the Agreement.
- 43. Drew seeks a declaration from this Court that PointCare's misconduct and purported termination of the Agreement constitute material breaches thereof.

FOURTH CAUSE OF ACTION

SPECIFIC PERFORMANCE

- 44. Drew repeats and realleges paragraphs 1 43 above.
- 45. The Agreement is a valid contract which exists between Drew and PointCare.
- 46. Drew has substantially performed its obligations under the Agreement and remains ready, willing and able to continue to perform its obligations under the Agreement.
 - 47. PointCare is able to perform its obligations under the Agreement.
- breaches of the Agreement, including its disclosure of Drew's confidential technological information and marketing plans, and cannot mitigate its damages. With respect to completion of the HT project, PointCare is the sole source provider of the CD4Sure assay, controls its patent rights, possesses the expertise relative to the assay and is able to complete the necessary compatibility testing with little capital cost. Drew, on the other

hand, cannot move the project forward unless and until PointCare satisfactorily completes its obligation.

49. As a result, PointCare should be ordered to specifically perform the Agreement until such time as it or Drew validly terminates the Agreement.

FIFTH CAUSE OF ACTION

FRAUDULENT INDUCEMENT

- 50. Drew repeats and realleges paragraphs 1 49 above.
- 51. By stating that it needed to reacquire the NP device to perform purported software upgrades thereto, PointCare knowingly misrepresented a material fact to Drew.
- 52. In reliance on PointCare's misrepresentation, Drew permitted PointCare to retrieve the NP device from Drew's Dallas headquarters.
- 53. PointCare's failure to return the NP device to Drew has resulted in significant detriment to Drew.

SIXTH CAUSE OF ACTION

CONVERSION

- 54. Drew repeats and realleges paragraphs 1 53 above.
- 55. Drew has a right of possession to the NP device.
- 56. PointCare has converted the NP device and is in the unauthorized possession thereof.

SEVENTH CAUSE OF ACTION

CONSTRUCTIVE TRUST

57. Drew repeats and realleges paragraphs 1 - 56 above.

- Having entered into a joint marketing agreement involving highly 58. sensitive technological information and confidential marketing plans, Drew and PointCare maintain a confidential or fiduciary relationship.
- In reliance on PointCare's promise to perform a purported software 59. upgrade on the NP device, Drew transferred possession of the device to PointCare, which has unlawfully retained possession thereof.
- As a result of this misconduct, PointCare has been unjustly enriched at the 60. expense of Drew.

EIGHTH CAUSE OF ACTION

TORTUOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

- Drew repeats and realleges paragraphs 1 60 above. 61.
- The Agreement is a valid contract knowingly entered into by Drew and 62. PointCare.
- Through its misconduct in unlawfully communicating with Drew's 63. distributors about marketing the NP device in geographic territories assigned to Drew, PointCare is intentionally procuring a breach of the their distribution agreement with Drew.
- As a direct result of PointCare's interference with Drew's current and 64. potential clients and business partners, Drew has suffered significant monetary and other damages.

NINTH CAUSE OF ACTION

BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

Drew repeats and realleges paragraphs 1 - 64 above. 65.

- 66. The Agreement is a valid contract which exists between Drew and PointCare and which is governed by New York law.
- 67. Drew has substantially performed its obligations under the Agreement and remains ready, willing and able to perform its obligations under the Agreement.
 - 68. PointCare is able to perform its obligations under the Agreement.
- 69. By failing to return Drew's NP device, disclosing highly confidential technological information and marketing plans, unlawfully communicating with Drew's distributors about marketing the NP device in geographic territories assigned to Drew, and violating its obligations to assist Drew by performing necessary testing of the CD4 assay's compatibility with the HT system, PointCare has breached the express terms and conditions of its Agreement with Drew as well as implied covenants of good faith and fair dealing that are implicit in every contract governed by New York law.

PRAYER FOR RELIEF

WHEREFORE, Drew demands as follows:

- (a) Judgment in its favor and against PointCare;
- (b) Permanent injunctive relief to prevent PointCare from seeking to distribute or soliciting the distribution of HT and NP products in territories assigned to Drew, terminating or otherwise violating its Agreement with Drew and communicating defamatory information to Drew's distributors;
 - (c) Damages, to the extent determinable, in an amount to be proven at trial;
- (d) Declaratory judgment that PointCare's misconduct and purported termination of the Agreement constitute material breaches thereof;
- (e) PointCare's specific performance of the Agreement, including the conducting of necessary testing of the HT machine and the return of the NP machine, until such time as it or

Drew validly terminates the Agreement;

- (f) Pre-judgment interest as allowed by law;
- Post-judgment interest as allowed by law; (g)
- Attorneys' fees and costs of court; (h)
- Such other, further and different relief as this Court may deem just and proper. (i)

Dated: New York, New York February 13, 2008

DUANE MORRIS LLP

Anthony J. Costantini John Dellaportas Brian/Damiano

1540 Broadway

New York, New York 10036 Telephone: (212) 692-1000 Facsimile: (212) 692-1020

Attorneys for Plaintiff Drew Scientific, Inc.

Manufacturing, Distribution and Co-Marketing Agreement

This Agreement, together with *Annexes 1 to 6* attached hereto and incorporated by reference ("Agreement") is made this _____ day of June, 2006 by and between PointCare Technologies, Inc., a company organized and existing under the laws of the Commonwealth of Massachusetts, with offices at 121 Cedar Hill Street, Marlborough, Massachusetts, USA ("POINTCARE"), and DREW SCIENTIFIC INC., a company organized and existing under the laws of Texas, with offices at 4230 Shilling Way, Dallas, Texas, USA ("DREW"). POINTCARE and DREW are sometimes hereinafter collectively referred to as the "Parties".

RECITALS

WHEREAS, POINTCARE develops, manufactures, and sells medical diagnostics that enable near patient care testing to be performed effectively, including POINTCARE'S proprietary CD4 Lymphocyte Enumeration Assay, CD4sure™.

WHEREAS, DREW, among other things, develops, manufactures, and sells *in vitro* diagnostic instrumentation platforms, including the Excell 22™, and associated consumables.

NOW THEREFORE, in consideration of the mutual promises and conditions herein contained, the Parties agree as follows:

Art. 1. Diagnostic Platform Development

1.1 DREW agrees to modify its current Excell 22™ hematology platform to accommodate POINTCARE'S proprietary CD4 Lymphocyte Enumeration Assay, CD4sure™. DREW will manufacture one modified version, called the 'HTc', which will be a full five part system that will be marketed and sold by DREW, and a second version, called the 'HTw', which be marketed and sold by POINTCARE for use in the treatment of patients with HIV infection. For purposes of this Agreement, these platforms will be referenced collectively as the 'high throughput' (HT) platform or individually as noted above. Among other things, a description of the two (2) diagnostic instrumentation platforms ('platforms'), as well as: (a) platform and assay specifications; (b) development responsibilities; (c) allocation of development costs; (d) development timetables; (e) performance parameters of the present CD4sure™ Assay and a

MUR PER

newly developed CD4Lymphocyte Enumeration Assay, as well as other assay-related performance standards; (f) performance parameters of the instrumentation platforms, as well as other platform-related performance standards; (g) responsibility for transfer of the developed platforms, the present CD4sure™ Assay, and the newly developed CD4 Lymphocyte Enumeration Assay into manufacturing; and (h) responsibility for incurred costs, as well as future costs, are set forth in *Annex 1* ("Specifications and Development Timelines for the DREW HT Platform and the POINTCARE CD4sure™ Lymphocyte Enumeration Assay Kit ") which is hereby included in this Agreement by reference.

POINTCARE hereby agrees to enter into a Development and Manufacturing agreement with a third party medical device manufacturer to jointly develop and manufacture the Near Patient (NP) instrumentation platform. Once developed, POINTCARE agrees that it will purchase, private label, and sell the NP instrumentation platform to DREW at prices, terms and conditions as noted in *Annex 2*. Further, POINTCARE shall grant DREW non-exclusive worldwide distribution rights for such NP platform. Such distribution rights will be conditional upon the successful development and marketing of the HT platform. A description of the NP platform, as well as: (a) platform and assay specifications; (b) development responsibilities; (c) allocation of development costs; (d) development timetables; (e) performance parameters of the CD4sure™ Assay, as well as other assay-related performance standards; (f) performance parameters of the instrumentation platform, as well as other platform and the CD4sure™ assay into manufacturing are set forth in *Annex 2* ("Specifications and Development Timelines for the NP Instrumentation Platform and the POINTCARE reformulated Lymphocyte Enumeration Assay Kit ").

MR PBR

- 1.2 Diagnostic Instrumentation Platform & CD4 Lymphocyte Enumeration Assay Kit Modifications.
 - 1.2.1 Except as otherwise provided in this Agreement, no instrumentation platform delivered by DREW, POINTCARE, or a third party manufacturer pursuant to this Agreement shall be modified or deviate from the agreed upon specifications noted in Annex 1 and/or Annex 2, except as may be jointly agreed upon by the Parties in writing. If an instrumentation platform is modified, the cost of developing the modified platform shall be allocated as stated in Annex 1 and/or Annex 2, as applicable. Any instrumentation platform unit price adjustment resulting from an agreed upon modification shall be negotiated in good faith by the Parties and shall be no more than the actual development and manufacturing costs. Any modification of the Platforms under this Article 1 shall be properly documented in writing and the corresponding Annex shall be modified accordingly.
 - 1.2.2 Except as otherwise provided in this Agreement, no CD4 Lymphocyte Enumeration Assay Kit delivered by POINTCARE hereunder shall be modified or deviate from the agreed upon specifications noted in *Annex 1* and/or *Annex 2*, except as may be jointly agreed upon by the Parties in writing. If a CD4 Lymphocyte Enumeration Assay Kit is modified, the cost of developing the modified platform shall be allocated as stated in *Annex 1* and/or *Annex 2*, as applicable. Any CD4 Lymphocyte Enumeration Assay Kit unit price adjustment resulting from an agreed upon modification shall be negotiated in good faith by the Parties and shall be no more than POINTCARE'S actual development and manufacturing costs. Any modification of the CD4 Lymphocyte Enumeration Assay Kit under this Article 1 shall be properly documented in writing and the corresponding *Annex* shall be modified accordingly.

MUR POK

1.3 Conformity and Compliance Standards.

- 1.3.1 POINTCARE represents and warrants that the CD4sure™ Assay, the reformulated CD4 Assay to be developed, and the NP instrumentation platform, will be manufactured, sold and distributed to DREW pursuant to the terms of this Agreement, will fully conform to all agreed upon specifications, and will fully conform to and comply with all applicable laws, rules and regulations of the United States, including but not limited to relevant provisions of the U.S. Food, Drug and Cosmetic (FD&C) Act and rules, regulations, guidelines and advisories issued pursuant to the FD&C Act. POINTCARE shall be solely responsible for all costs associated with securing any necessary U.S. FDA approvals to market and sell the CD4 Lymphocyte Enumeration Assays that will be used and/or developed for use with the HT and NP diagnostic instrumentation platforms unless otherwise agreed upon in writing by the Parties. Further, POINTCARE shall be responsible for all costs associated with securing U.S. FDA approval to market and sell the NP diagnostic instrumentation platforms developed under this Agreement unless otherwise agreed upon in writing by the Parties.
- 1.3.2 DREW represents and warrants that any HT diagnostic instrumentation platforms manufactured, sold and distributed to POINTCARE pursuant to the terms of this Agreement, will fully conform to agreed upon specifications, and will conform to and comply with all applicable laws, rules and regulations of the United States, including but not limited to relevant provisions of the U.S. Food, Drug and Cosmetic (FD&C) Act and rules, regulations, guidelines and advisories issued pursuant to the FD&C Act. DREW shall be solely responsible for all costs associated with securing U.S. FDA approval to market and sell the HT diagnostic instrumentation platforms developed under this Agreement unless otherwise agreed upon in writing by the Parties.
- **1.3.3** POINTCARE and DREW, at their respective option, may seek regulatory approvals or effect registrations necessary to sell and distribute the assays and the platforms in certain countries that are encompassed within the marketing and sales territories, as defined in *Annex 3*. POINTCARE and DREW agree to act in good faith to support the other Party's efforts to obtain such approvals or effect such registrations by supplying information in their possession that is necessary for the preparation of



submissions to relevant regulatory agencies and by providing consultations through knowledgeable technical representatives upon written request in accordance with the terms set forth in Annex 3.

- 1.3.4 Both Parties to this Agreement shall have the right to appoint any of their respective subsidiaries, affiliates, distributors and/or sub-distributors, to resell or market the products encompassed within this Agreement, consistent with the terms and conditions of this Agreement.
- 1.3.5 DREW and POINTCARE represent and warrant that they have secured or will secure the necessary International Standards Organization ("ISO") certification for medical devices for the instrumentation platforms developed pursuant to this Agreement (DREW will secure for the HT platforms and POINTCARE will secure for the NP platform). During the Term of this Agreement, DREW and POINTCARE will comply with applicable ISO requirements with respect to the diagnostic instrumentation platforms. DREW and POINTCARE shall require that a device history record be properly maintained and kept for each diagnostic instrumentation platform that is manufactured and sold to a Party pursuant to this Agreement and further agree that such records shall be made available to each Party for review upon reasonable request, during normal business hours...
- 1.3.6 POINTCARE and DREW shall cooperate in meeting applicable requirements and the guidelines published by the FDA, ISO and other relevant governmental regulatory agencies. POINTCARE and DREW shall use their best efforts and work cooperatively to answer specific questions relating to quality assurance that are received from any government or regulatory agency. In the event that either POINTCARE or DREW receives notice of non-compliance with any applicable government or quasi-government law or regulation, the notified Party shall immediately provide the other Party with written notice of such purported non-compliance. Each Party shall notify the other Party promptly in writing if it becomes aware of any defect or condition which may render any CD4 assay or platform that is a part of this Agreement pursuant to Annex 1 and/or Annex 2 to be in violation of any applicable law or regulation.



1.3.7 The Parties agree to label the products manufactured pursuant to this Agreement in compliance with applicable laws and regulations, as well as the terms and conditions contained in **Annex 4** of this Agreement.

Art. 2. Terms of Purchase and Supply.

- 2.1 During the Term of this Agreement and subject to the terms and conditions included in this Agreement, DREW shall purchase all CD4 test kits for use with the HT and NP instrumentation platforms exclusively from POINTCARE as set forth in *Annex 5*.
- 2.2 During the period that this Agreement remains effective and subject to the terms and conditions included in this Agreement, POINTCARE shall purchase the HTw instrumentation platform, as well as any replacement or spare parts for the HTw instrumentation platform, exclusively from DREW for use with POINTCARE's CD4 Lymphocyte Enumeration Assay Kits as set forth in *Annex 5*.
- 2.3 POINTCARE agrees to fill with reasonable promptness, all orders from DREW for its CD4 Lymphocyte Enumeration Assay Kits and NP instrumentation platforms that are approved and accepted by POINTCARE. Upon receipt of an order from DREW, POINTCARE will acknowledge receipt and provide an estimated date of shipment. At no time during the term of this Agreement shall the period between acceptance of a DREW purchase order and the shipment by POINTCARE to DREW exceed eight (8) weeks, unless mutually agreed upon by the Parties. In the instance of a supply limitation, POINTCARE agrees to ship a pro rata percentage of its existing inventory and production capacity at the time of supply limitation to DREW on the basis of each Party's average monthly volume requirements during the past three (3) months (or less if such shortage should occur before a full three months of supply information is available).
- 2.4 DREW agrees to fill, with reasonable promptness, all orders from POINTCARE for its HTw instrumentation platform that are approved and accepted by DREW. Upon receipt of an order from POINTCARE, DREW will acknowledge receipt and provide an estimated date of shipment. At no time during the term of this Agreement shall the period between acceptance of a POINTCARE purchase order and the shipment by DREW of its HTw instrumentation

MR BK

platform to POINTCARE exceed eight (8) weeks, unless mutually agreed upon by the Parties. Delivery terms for spare/replacement parts and other consumables shall be confirmed by DREW upon receipt of a written purchase order from POINTCARE. DREW will use its best efforts to deliver HTw instrumentation platforms or spare parts purchased hereunder within the delivery terms requested by POINTCARE, subject to the Warranty (Article 3) and other applicable provisions of this Agreement.

POINTCARE agrees that any agreement that it enters with a third party developer/manufacturer relative to the development and manufacture of the NP instrumentation platform shall require said third party manufacturer to fill with reasonable promptness, all orders from POINTCARE for the NP instrumentation platform that are approved and accepted. Upon receipt of an order from POINTCARE, the third party manufacturer shall be required to acknowledge receipt and provide an estimated date of shipment.

- 2.5 The prices that POINTCARE shall pay to DREW for the purchase of DREW's HTw instrumentation platform, as well any spare/replacement parts that are requested, and the price that DREW shall pay to POINTCARE for the purchase of POINTCARE's NP instrumentation platform, as well any spare/replacement parts that are requested, and its CD4 Lymphocyte Enumeration assay kits are set forth in *Annex 5*. Said costs shall include the cost of proper packaging for shipment per the specifications included in *Annex 1* and *Annex 2*. The Party that orders the product shall be fully responsible for the actual cost of shipping and insurance. Title to the purchased product(s) and the risk of loss or damage shall shift to the purchaser upon delivery to the purchaser, the purchaser's agent, the purchaser's representative, or a mutually acceptable transport company.
- 2.6 Any price adjustments sought by either Party relative to a product or service that is included in this Agreement must be in accordance with the terms and conditions set forth in *Annex 5*.
- **2.7** The payment terms that are applicable to any product or service that is included in this Agreement are included in *Annex 5*.



- 2.8 During the Term of this Agreement, POINTCARE shall not manufacture, market, sell or distribute any instrumentation platform that is substantially equivalent with the DREW HT diagnostic instrumentation platforms with regard to test menu and performance, without DREW'S prior express written agreement, which will not be unreasonably withheld. Further, POINTCARE shall not distribute, market or sell any diagnostic instrumentation platform under any trade name, trademark or logo that is the legal property of DREW without first obtaining DREW's prior written consent.
- 2.9 In case of a change of control of POINTCARE, DREW shall have the option to manufacture, or have manufactured, all reagents necessary to perform the CD4 Lymphocyte Enumeration Assay. POINTCARE will fully cooperate with DREW and execute an appropriate license agreement for the transfer by POINTCARE of know-how and technologies that are necessary to manufacture the CD4 Lymphocyte Enumeration Assay Kits provided that DREW and its third party manufacturer recognize in the license agreement the legal rights which POINTCARE possesses with respect to any know-how or technology. Such license agreement shall include a provision that acknowledges DREW's obligation to pay POINTCARE a continuing licensing royalty equal to five (5) percent of the sales price of each CD4 Lymphocyte Enumeration Assay Kit which it sells for use with the HT or NP instrumentation platforms.
- 2.10 In case of a change of control of POINTCARE, DREW shall also have the right to directly enter into an agreement with the third party manufacturer of the NP instrumentation platform, C2D, at any time that it deems appropriate and to purchase the NP instrumentation platform directly from said manufacturer rather than POINTCARE.

Art. 3. Warranty:

3.1 POINTCARE hereby represents and warrants to DREW that the NP instrumentation platforms and GD4 Lymphocyte Enumeration Assay Kits that it sells or otherwise provides to DREW hereunder will conform to the Product Specifications set forth in *Annex 2.* Further, POINTCARE hereby represents and warrants to DREW that any modifications thereto, will be in compliance with all applicable laws and regulations and will be free from defects in material,



workmanship and design. If any POINTCARE CD4 Lymphocyte Enumeration Assay Kit sold to DREW is recalled by POINTCARE or its third party manufacturer and otherwise is not capable of being legally sold or used with the HTc or NP instrumentation platforms through no fault or error on the part of DREW, POINTCARE agrees to promptly replace said CD4 testing kit(s), at its full expense (including the cost of shipping and insurance), provided such CD4 testing kit(s) are not beyond the expiration date noted on said CD4 testing kit(s) at the time when DREW places POINTCARE on notice of such product return. DREW agrees to return any CD4 testing kits that it cannot sell for the above noted reasons directly to POINTCARE or its designated agent, at POINTCARE's cost. Further, NP instrumentation platforms and parts that are sold or otherwise provided by POINTCARE to DREW under this Agreement shall be warranted for a period of fifteen (15) months from the date of shipment from POINTCARE to DREW or for a period of twelve (12) months from the date that the NP instrumentation platform or part was provided to DREW's customer or end-user, whichever expires first. DREW agrees to secure, maintain and provide to POINTCARE, upon request, a certification, signed by a representative of the customer and/or end-user that confirms the date of customer and/or end user receipt.

- 3.2 DREW hereby agrees that any HTw instrumentation platform and spare/replacement parts sold or otherwise provided hereunder shall conform to the Product Specifications set forth in *Annex 1*, as applicable. Further, DREW agrees that any HTw instrumentation platform or parts modifications shall be in compliance with all applicable laws and regulations and will be free from defects in material, workmanship and design. DREW instrumentation platforms and parts that are sold or otherwise provided to POINTCARE under this Agreement shall be warranted for a period of fifteen (15) months from the date of shipment from DREW to POINTCARE or for a period of twelve (12) months from the date that the instrumentation platform or part was provided to POINTCARE's customer or end-user, whichever expires first. POINTCARE agrees to secure, maintain and provide to DREW upon request, a certification, signed by a representative of the customer and/or end-user that confirms the date of customer and/or end user receipt.
- 3.3 Neither POINTCARE nor DREW provides the other Party with any other warranties, whether expressed or implied. In no event will DREW or POINTCARE be liable to each other or any other person for direct or indirect, remote or consequential damages related to the



incorrect use of their respective instrumentation platforms, including but not limited to commercial losses and tort claims of any kind.

- 3.4 Notwithstanding any contrary terms in this Agreement, POINTCARE agrees to indemnify, defend and hold DREW harmless from and against any and all losses, claims, actions, costs, expenses and damages, including reasonable attorney's fees and expenses, that arise out of a breach of any warranty contained in this Agreement or out of any product liability claim or action that relates to any POINTCARE product sold or otherwise provided pursuant to this Agreement, except to the extent that such loss, claim, action, cost, expense, or damage arises from: a) acts or omissions that are negligent, reckless or deemed to represent willful misconduct on the part of DREW or its subsidiaries or any of their agents or distributors; or, b) representations made by DREW or its subsidiaries or any of their agents or distributors beyond those made by POINTCARE. In connection with such indemnifications, DREW agrees to notify POINTCARE of any such claim, pursuant to the Notice provisions of this Agreement, within five (5) business days of receipt of notice by DREW's legal counsel and to cooperate with POINTCARE, at POINTCARE'S expense, in the defense of any such claim.
- 3.5 Notwithstanding any contrary terms in this Agreement, DREW agrees to indemnify, defend and hold POINTCARE harmless from and against any and all losses, claims, actions, costs, expenses and damages, including reasonable attorney's fees and expenses, that arise out of a breach of any warranty contained in this Agreement or out of any product liability claim or action that relates to any DREW product sold or otherwise provided pursuant to this Agreement, except to the extent that such loss, claim, action, cost, expense, or damage arises from a): acts or omissions that are negligent, reckless or deemed to represent willful misconduct on the part of POINTCARE or its subsidiaries or any of their agents or distributors; or, b) representations made by POINTCARE or its subsidiaries or any of their agents or distributors beyond those made by DREW. In connection with such indemnifications, POINTCARE agrees to notify DREW of any such claim, pursuant to the Notice provisions of this Agreement, within five (5) business days of receipt of notice by POINTCARE's legal counsel and to cooperate with DREW, at DREW's expense, in the defense of any such claim.
- 3.6 POINTCARE agrees to procure and maintain product liability and general liability insurances naming DREW as an additional insured, with minimum limits of coverage as noted



in Annex 5. POINTCARE shall, on or before delivery of NP instrumentation platforms and/or CD4 Lymphocyte Enumeration Assay Kits, furnish DREW with certificates of insurance evidencing the foregoing coverages and limits. Such insurance policies shall not be cancelled or changed without adequate replacement and without providing DREW with thirty (30) days advance written notice of such replacement.

- 3.7 DREW agrees to procure and maintain product liability and general liability insurances naming POINTCARE as an additional insured, with minimum limits of coverage as noted in Annex 5. DREW shall, on or before delivery of its HTw instrumentation platform, furnish POINTCARE with certificates of insurance evidencing the foregoing coverages and limits. Such insurance policies shall not be cancelled or changed without adequate replacement and without providing POINTCARE with thirty (30) days advance written notice of such replacement.
- 3.8 POINTCARE agrees to require the third party manufacturer of the NP instrumentation platform to procure and maintain product liability and general liability insurances.

Art. 4. Installation, maintenance and repairs of Instrumentation Platforms.

4.1 POINTCARE and/or its agents, representatives and/or affiliates, shall be responsible for the installation, set-up, and repair of all DREW HTw instrumentation platforms purchased pursuant to this Agreement at all POINTCARE customer or end-user facilities. POINTCARE also assumes responsibility to provide any needed maintenance service and to provide requested technical support to its customers and end-users relative to the operation, use, care and maintenance of DREW HTw instrumentation platforms. Unless specifically set forth in Annex 6 of this Agreement, DREW shall not be responsible for installing or repairing DREW HTw instrumentation platforms provided to POINTCARE under this Agreement. Further, unless specifically noted in Annex 6, DREW shall bear no responsibility to provide technical support or training to POINTCARE'S employees, agents, representatives, customers or endusers.

DREW and/or its agents, representatives and/or affiliates, shall be responsible for the installation, set-up, and repair of all POINTCARE NP instrumentation platforms purchased

MIR BX

pursuant to this Agreement at all DREW customer or end-user facilities. DREW also assumes responsibility to provide any needed maintenance service and to provide requested technical support to its customers and end-users relative to the operation, use, care and maintenance of POINTCARE NP instrumentation platforms. Further, unless specifically noted in *Annex 6*, POINTCARE shall bear no responsibility to provide technical support or training to DREW's employees, agents, representatives, customers or end-users.

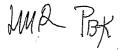
4.2 POINTCARE agrees that it shall only use spare/replacement parts purchased from DREW to repair or service any DREW instrumentation platform procured pursuant to this Agreement. In the event that POINTCARE or its employees, agents, representatives, customers or end-users use parts purchased from a person or entity not related to DREW, without the specific written approval of DREW, any and all warranties, including but not limited to the warranty against material defects and manufacturing flaws, shall be deemed null and void.

DREW agrees that it shall only use spare/replacement parts purchased from POINTCARE to repair or service any POINTCARE instrumentation platform procured pursuant to this Agreement. In the event that DREW or its employees, agents, representatives, customers or end-users use parts purchased from a person or entity not related to POINTCARE, without the specific written approval of POINTCARE, any and all warranties, including but not limited to the warranty against material defects and manufacturing flaws, shall be deemed null and void.

4.3 DREW does maintain a competent team of technical specialists that are knowledgeable concerning its instrumentation platforms. DREW agrees to reasonably consider a request for technical assistance by POINTCARE that is not agreed upon in *Annex 6* and to make a reasonable effort to provide an application/service specialist to support POINTCARE and its customer or end-user pursuant to the relevant reimbursement and support terms contained in *Annex 6*.

Art. 5. Intellectual property.

5.1 All patents, trademarks, trade names, labels and copyrights currently proprietary to POINTCARE ("POINTCARE Intellectual Property") shall remain the exclusive property of



POINTCARE. POINTCARE shall have the exclusive right to all future modifications and additions to POINTCARE'S Intellectual Property, as well as intellectual property developed in the future by POINTCARE provided such modifications, additions, and/or developments are not the result of the direct involvement or financial assistance of DREW. DREW shall not have the right to and shall not apply for any patent(s) relating to POINTCARE Intellectual Property that is solely developed by POINTCARE, at its own cost, during the term of this Agreement and thereafter.

- All patents, trademarks, trade names, labels and copyrights currently proprietary to DREW ("DREW Intellectual Property") shall remain the exclusive property of DREW. DREW shall have the exclusive right to all future modifications and additions to DREW'S Intellectual Property as well as intellectual property developed by DREW provided such modifications, additions, and/or developments are not the result of the direct involvement or financial assistance of POINTCARE. POINTCARE shall not have the right to and shall not apply for any patent(s) relating to DREW Intellectual Property which is solely developed by DREW, at its own cost, during the term of this Agreement and thereafter.
- 5.3 All intellectual property that is jointly developed by the Parties during the Term of the Agreement shall be deemed to be jointly owned by the Parties, provided that a brief summary of the invention is described in writing within 10 business days from the date of the invention and signed by both Parties. Subsequently, both Parties shall agree to a percent ownership of the invention. If such an agreement can not be reached after reasonable discussions among the Parties, the ownership of the invention shall be finally determined by an arbitrator as provided below in this section. The Parties shall be responsible for all costs incurred in the protection or defense of the intellectual property according to their percent ownership of the intellectual property. Both Parties shall be free to use the joint invention and develop, make and sell products based on the jointly owned intellectual property, without seeking the consent of the other Party. Each Party agrees to negotiate a reasonable royalty to be paid to the other Party based upon sales that it makes or that its licensee makes, of products and/or processes that use or incorporate the intellectual property. The percent ownership in the intellectual property, the cost of product development and other reasonable factors shall be considered in the determination of a reasonable royalty. Should the Parties be unable to agree on a royalty rate, they will submit the issue to binding arbitration as described below in this Section.



If a Party should desire to sell its rights to any intellectual property that was jointly developed pursuant to this Agreement, the Parties will act in a commercially reasonable manner to achieve a valuation of the property rights of the Party that seeks to divest its rights and the other Party shall have the right of first refusal with respect to said property. If, after best efforts, an agreement cannot be reached between the Parties regarding a commercially appropriate valuation, the Parties agree that they will select a mutually acceptable arbitrator to establish a valuation that will be deemed binding upon the Parties. The costs of the arbitrator, as well as the arbitration proceeding, will be equally divided between the Parties. The arbitrator will have the authority to set forth guidelines for the submission of evidence, expert reports and testimony. However, it is agreed that no oral testimony will be included in the proceeding and that the Federal Rules of Civil Procedure and Evidence will otherwise govern such proceedings. Each Party will be responsible for its own costs associated with resolving such a disagreement.

- 5.4 Notwithstanding the other provisions of this Article 5, POINTCARE shall supply to DREW, in electronic, editable format (such as Microsoft Word), information, manuals and documentation sufficient for DREW'S development of its own product manuals, promotional materials and related documentation for distribution to its agents, distributors and current or prospective end-users. DREW shall have the exclusive right to copyright the manuals, promotional materials and other documentation that develops. All of the documents developed and distributed under this Article 5.4 shall bear DREW's logo and/or trade dress unless the Parties agree otherwise in writing.
- POINTCARE, in electronic, editable format (such as Microsoft Word), information, manuals and documentation sufficient for POINTCARE'S development of its own product manuals, promotional materials and related documentation for distribution to its agents, distributors and current or prospective end-users. POINTCARE shall have the exclusive right to copyright the manuals, promotional materials and other documentation that it develops. All of the documents developed and distributed under this Article 5.5 shall bear POINTCARE'S logo and/or trade dress unless the Parties agree otherwise in writing.

MUR BK

Art. 6. Term and Termination

- 6.1 With respect to combined use of DREW'S HT instrumentation platforms and POINTCARE'S CD4sure™ assays, this Agreement shall be effective for a term of five (5) years commencing on the date that DREW receives U.S. FDA approval to sell the HTc and HTw platforms, as modified to accommodate POINTCARE's CD4sure™ assay, or POINTCARE receives U.S. FDA approval to sell its modified CD4sure™ assay, whichever approval is later received ('Anniversary Date'), and end on the fifth anniversary of the Anniversary Date. Unless lawfully terminated, the provisions of this Agreement pertaining specifically to the supply to DREW by POINTCARE of its CD4 Lymphocyte Enumeration Assay Kits for use with the HTc shall be automatically renewed at the option of DREW for a successive five (5) year period unless DREW provides POINTCARE with written notice of its desire not to renew the Agreement no less than ninety (90) days prior to Anniversary Date. DREW shall have the right to renew this Agreement with respect to the aforementioned CD4 Lymphocyte Enumeration Assay Kits for a total of three (3) successive five (5) year periods following the initial term with the proviso that if POINTCARE no longer desires to manufacture and sell CD4 Lymphocyte Enumeration Assay Kits to DREW, it shall provide DREW, at no cost, with the licenses, know-how and technical support necessary to allow DREW or its designated third party manufacturer to manufacture and sell the CD4 Lymphocyte Enumeration Assay Kits and DREW shall agree to pay POINTCARE a royalty in the amount of five percent (5%) of the sales price per CD4 Lymphocyte Enumeration Assay Kit sold.
- 6.2 With respect to combined use of the NP instrumentation platform and CD4 Lymphocyte Enumeration Assay Kits that POINTCARE shall develop, this Agreement shall be effective for a period of five (5) years ("NP Term") commencing on the date that U.S. FDA approval is received to sell the NP platform or the date that POINTCARE receives FDA approval to sell its modified CD4 Lymphocyte Enumeration Assay Kits for the NP instrumentation platform in the United States, whichever approval is later received ('NP Anniversary Date') and ending on the fifth anniversary of the NP Anniversary Date. Unless the Agreement is lawfully terminated in accordance with the provisions of this Agreement, the provisions of this Agreement pertaining to the supply to DREW by POINTCARE of the NP instrumentation platform shall be capable of renewal for successive five (5) year terms, at the option of DREW, provided that DREW provides notice no less than thirty (30) days prior to the expiration of an NP Term, that C2 will



continue to supply the NP instrumentation platform to POINTCARE, and the Parties, acting in good faith, reach consensus on renegotiated pricing terms. With respect to the modified CD4 Lymphocyte Emumeration Assay Kit for use with the NP platform, it is agreed that DREW has the right to renew this Agreement for successive five (5) year terms provided that DREW provides notice no less than thirty (30) days prior to the expiration of an NP Term and that POINTCARE desires to continue to manufacture and sell said CD4 Assay Kits to DREW. If, after the initial term of this Agreement, POINTCARE no longer desires to supply DREW with the CD4 Assay Kits for use with the NP platform, it shall provide DREW, at no cost, with the licenses, know-how and technical support necessary to allow DREW or its designated third party manufacture to manufacture and sell the modified CD4 Lymphocyte Enumeration Assay Kits for use with the NP instrumentation platform and DREW shall agree to pay POINTCARE a royalty in the amount of five percent (5%) of the sales price per CD4 Lymphocyte Enumeration Assay Kit sold.

- POINTCARE NP instrumentation platform purchases by POINTCARE and POINTCARE NP instrumentation platform purchases by DREW, it is agreed that if this Agreement is lawfully terminated or at the conclusion of its initial term, each Party shall respectively have an independent option to purchase said instrumentation platforms from any manufacturer that they choose or to continue in the relationship defined by this Agreement. Notice must be provided in accordance with the terms of this Agreement. Further, the Parties agree that DREW and POINTCARE shall, upon lawful termination or at the conclusion of the Agreement's initial term, have an independent option to negotiate an agreement upon substantially similar terms that will allow each Party to continue to distribute products provided by the other party in the Territories as agreed upon herein or as amended in writing. While no Party shall be required to enter into such an arrangement, the Parties acknowledge that consent to enter into such an arrangement shall not be unreasonably withheld.
- 6.4 Neither Party shall be liable to the other for damages resulting from the lawful expiration or termination of this Agreement pursuant to this Article 6.
- **6.5** POINTCARE shall be obligated to manufacture and supply to DREW all NP instrumentation platforms and spare/replacement parts, as well as CD4 Lymphocyte Enumeration Assay Kits, ordered by DREW pursuant to this Agreement prior to the expiration



or termination of this Agreement, provided that such order was received and accepted by POINTCARE prior to such expiration or termination.

- **6.6.** DREW shall be obligated to manufacture and supply to POINTCARE all HTw instrumentation platforms and spare/replacement parts ordered by POINTCARE pursuant to this Agreement prior to the expiration or termination of this Agreement, provided that such order was received and accepted by DREW prior to such expiration or termination.
- 6.7 If a Party fails to submit any payment due hereunder more than five (5) days after the due date, a written non-payment notice of such non-payment may be issued to the delinquent Party. If a Party has issued three (3) successive notices of non-payment to the other Party, it may terminate this agreement five (5) days after receipt of the third notice, pursuant to Sections 8.4 and 8.5, unless the deficiency is fully satisfied prior to receipt of the written termination notice.
- 6.8 Notwithstanding any provision in this Agreement to the contrary, upon expiration or termination of this Agreement for any reason, each Party shall continue to supply requested product for a period of up to seven years if legally necessary to comply with any applicable laws and regulations of countries in which a Party sells the CD4 Lymphocyte Enumeration Assays Kits, the DREW HT instrumentation platforms and/or the POINTCARE NP instrumentation platform.

6.9 Either Party may terminate this Agreement:

- (a) in the event of a material breach by the other Party of any of the terms and conditions of the Agreement, excepting breach resulting from non-payment of any disputed amounts due hereunder, by giving the other Party written notice of such breach, and provided that such breach shall not have been cured within sixty (60) days of such notice; or
- (b) Immediately, by written notice thereof, if any of the following events or an event analogous thereto occurs:



- (i) an adjudication has been made that the other Party is bankrupt or insolvent;
- (ii) the other Party has filed bankruptcy proceedings or has had such proceedings filed against it, except as part of a bona fide scheme for reorganization;
- (iii) a receiver has been appointed for all or substantially all of the property of the other Party;
- (iv) the other Party has assigned or attempted to assign this Agreement for the benefit of its creditors; or
- (v) the other Party has begun any proceeding for the liquidation or winding up of its business affairs.

HTw diagnostic instrumentation platforms as required under the terms of this Agreement, including but not limited to the product specifications included in *Annex 1* and to the extent that DREW's inability to perform under this Agreement is not excused by this Agreement or a subsequent written agreement of the Parties, POINTCARE shall have the right to directly manufacture the diagnostic instrumentation platforms or to have the platforms manufactured by a mutually acceptable third party. DREW will fully cooperate with POINTCARE and execute an appropriate license agreement for the transfer by DREW of know-how and technologies that are necessary to manufacture the diagnostic instrumentation platforms provided that POINTCARE and its third party manufacturer recognize in the license agreement the legal rights which DREW possesses with respect to any know-how or technology. The Parties will negotiate an appropriate licensing fee in good faith. If, after best efforts, the Parties cannot agree to a mutually acceptable licensing fee and agreement, the Parties shall select a mutually acceptable arbitrator and proceed in accordance with the arbitration process that is included in Section 5.3 of this Agreement.

LMR Pox

Moreover, should DREW close down or otherwise divest its manufacturing facility or facilities that are necessary for the manufacture of the DREW HTw diagnostic instrumentation platform, POINTCARE shall have the right of first refusal to purchase said facility/facilities at fair market value, which shall be set by a mutually agreed upon third party appraiser. If DREW is unable to meet its obligations to POINTCARE as a result of the sale of its manufacturing facility/facilities and POINTCARE would choose not to purchase the facility/facilities but still desires to secure its requirements of the DREW HTw diagnostic instrumentation platform, DREW will agree to provide POINTCARE with a license under which DREW shall transfer the know-how and technologies that are necessary to manufacture the HTw diagnostic instrumentation platform. The Parties will negotiate an appropriate licensing fee in good faith. If, after best efforts, the Parties cannot agree to a mutually acceptable licensing fee and agreement, the Parties shall select a mutually acceptable arbitrator and proceed in accordance with the binding arbitration process that is included in Section 5.3 of this Agreement.

6.11 In the event that POINTCARE is unable to deliver to DREW its requirements of POINTCARE CD4 Lymphocyte Enumeration Assay Kits, as required under the terms of this Agreement, including but not limited to the product specifications included in Annex 1 and Annex 2, and to the extent that POINTCARE's inability to perform under this Agreement is not excused by this Agreement or a subsequent written agreement of the Parties, DREW shall have the right to directly manufacture the CD4 Lymphocyte Enumeration Assay Kits or to have the CD4 Lymphocyte Enumeration Assay Kits manufactured by a mutually acceptable third party. POINTCARE will fully cooperate with DREW and execute an appropriate license agreement for the transfer by POINTCARE of know-how and technologies that are necessary to manufacture the CD4 Lymphocyte Enumeration Assay Kits provided that DREW and its third party manufacturer recognize in the license agreement the legal rights which POINTCARE possesses with respect to any know-how or technology. The Parties will negotiate an appropriate licensing fee in good faith. If, after best efforts, the Parties cannot agree to a mutually acceptable licensing fee and agreement, the Parties shall select a mutually acceptable arbitrator and proceed in accordance with the binding arbitration process that is included in Section 5.3 of this Agreement.

Moreover, should POINTCARE close down or otherwise divest its manufacturing facility or facilities that are necessary for the manufacture of the CD4 Lymphocyte Enumeration Assay

MR Be

Kits, DREW shall have the right of first refusal to purchase said facility/facilities at fair market value, which shall be set by a mutually agreed upon third party appraiser. Should POINTCARE receive a credible offer to buy all of its operations or a portion of its operations that would affect its ability to supply DREW'S requirements for CD4 Lymphocyte Enumeration Assay Kits, POINTCARE agrees that DREW shall have the right to make an offer that exceeds the other credible offer and that POINTCARE shall be obligated to accept such offer from DREW. If POINTCARE is unable to meet its obligations to DREW as a result of the sale of its manufacturing facility/facilities and DREW would choose not to purchase the facility/facilities but still desires to secure its requirements of the CD4 Lymphocyte Enumeration Assay Kits, POINTCARE will agree to provide DREW with a license under which POINTCARE shall transfer the know-how and technologies that are necessary to manufacture the CD4 Lymphocyte Enumeration Assay Kits. The Parties will negotiate an appropriate licensing fee in good faith. If, after best efforts, the Parties cannot agree to a mutually acceptable licensing fee and agreement, the Parties shall select a mutually acceptable arbitrator and proceed in accordance with the binding arbitration process that is included in Section 5.3 of this Agreement.

- 6.12 Following the termination of this Agreement (whether by non-renewal or termination pursuant to Article 6), each Party to this Agreement shall have the right to continue distributing the diagnostic instrumentation platforms and/or the CD4 Lymphocyte Enumeration Assay Kits as follows:
 - DREW agrees that it will sell to POINTCARE its requirements of accessories, 6.12.1 supplies and spare parts for the HTw platform at all times during the Term and for seven (7) years after the termination of this Agreement at pricing and terms that are in accordance with this Agreement. Such sales shall be governed by the terms of this Agreement, even though this Agreement may have been terminated. Should the Agreement be terminated and DREW cannot deliver spare parts within the agreed time frame, POINTCARE may repair, or refurbish or source from third parties equivalent spare parts for the HTw platform. DREW shall furnish to POINTCARE all information necessary to enable POINTCARE to source such parts and, if necessary, actively support POINTCARE's effort to do so. In such cases, DREW shall bear no risk and shall not be subject to any liability for any such product that it does not directly sell to POINTCARE.
 - POINTCARE agrees to sell to DREW its requirements of accessories, supplies and spare parts for the NP instrumentation platform, as well as the CD4 Lymphocyte Enumeration Test Kits for the HTc platform and the NP platform at all times during the



Term, and for seven (7) years after the termination of this Agreement at the pricing and the terms provided herein. Such sales shall be governed by the terms of this Agreement, even though this Agreement may have been terminated. Should the Agreement be terminated and POINTCARE cannot deliver such NP instrumentation platforms and/or CD4 assay kits within the agreed time frame, DREW may source the undeliverable product from third parties. POINTCARE shall furnish to DREW all information necessary to enable DREW to source such instrumentation platform and/or CD4 assay kits and, if necessary, actively support DREW's effort to do so. In such cases, POINTCARE shall bear no risk and shall not be subject to any liability for any such NP instrumentation platforms and/or CD4 Assay Kits that it does not directly sell to DREW.

6.13 Termination or non-renewal of this Agreement shall not in any way operate so as to impair or destroy any of the rights or remedies of POINTCARE or DREW, whether at law or in equity, nor shall it relieve the Parties of their obligations pursuant to Articles 3, 5, and 7 and Sections 8.1, 8.4, and 8.5 of this Agreement.

Art. 7 Confidentiality:

7.1 Each Party shall maintain in confidence both the terms of this Agreement and any information received from the other Party in writing during the term of this Agreement and shall neither publish, disseminate nor disclose such information to any third Party nor use such information except for the furtherance of the purposes of this Agreement, without the prior express written permission of such other Party. This obligation shall not apply to any information which: (i) now or hereafter comes into the public domain, except by breach of this Agreement, or (ii) is already in the possession of the receiving Party other than as a result of having received it from the disclosing Party as evidenced by written records, or (iii) is independently developed by the receiving Party without use of or access to the information of the disclosing Party, or (iv) which is required to be provided to a governmental regulatory agency in order to secure the necessary regulatory approvals to manufacture or market the products, or (v) is required to be disclosed by a Subpoena issued from a court of competent jurisdiction, a Court Order or a civil investigative demand; provided that the receiving Party, subject to such requirement of this subparagraph (v): (a) promptly notifies the other Party and co-operates with efforts to make such disclosure in confidence or subject to a suitable Protective Order; and (b) the receiving Party discloses only so much of the confidential information as its counsel advises is required to comply with such requirement; or (vi) is



intended to be used by an agent, affiliate and/or end-user of DREW or POINTCARE. The obligations of this Article 7 shall extend to any agent, employee, affiliate, and/or end-user that is provided, in whole or in part, with this Agreement. Moreover, the obligations of Article 7 shall continue for five (5) years after the expiration or termination of this Agreement. Upon expiration or termination of this Agreement, each Party shall, at the other's request, destroy or return to the other Party all copies of any information provided pursuant to this Agreement, including all information provided to any agent, employee, affiliate, and/or end-user. However, counsel for each Party to this Agreement may retain one (1) copy of such information solely for the purpose of monitoring compliance with the obligation of confidentiality under this Agreement.

7.2 Each Party agrees not to recruit any member of staff or employee of the other Party for a possible employment or independent assignment within their organization or any affiliated organizations, either as an employee or independent consultant or in any other capacity, without the previous agreement of the other Party. These obligations shall remain in force during the term of this Agreement and for a period of one (1) year after expiration or termination of this Agreement.

Art. 8. MISCELLANEOUS

- 8.1 Binding Effect and Assignment. This Agreement shall inure to the benefit of and be binding upon each of the Parties hereto and their respective successors and assigns. Nevertheless, neither this Agreement, nor any right or obligation of a Party arising from this Agreement, may be assigned by such Party without the prior written approval of the other Party, such approval not to be unreasonably withheld, except that DREW may assign this Agreement and such rights and obligations to a purchaser or other transferee of its entire business, without such written approval from POINTCARE. The benefits to DREW under this Agreement are also available to DREW'S subsidiaries and affiliate companies, and DREW shall be responsible for any such subsidiary or affiliate to POINTCARE hereunder, if same are not met.
- 8.2 Entire Agreement and Modifications. This Agreement (including the Annexes hereto), together with the Confidentiality Agreement between the Parties dated November 18, 2005, sets forth the entire Agreement between the Parties and supersedes any and all prior or



contemporaneous negotiations, agreements, representations, understandings and commitments concerning the subject matter hereof. This Agreement shall take precedence over all conflicting or inconsistent terms, conditions or provisions on any invoice or purchase order. Any alteration, amendment or modification to any term or provision of this Agreement shall be in writing and signed by duly authorized officers of POINTCARE and DREW.

- 8.3 Force Majeure. If the full or partial performance of this Agreement or any obligation hereunder is prevented, restricted or interfered with by reason of any cause beyond the control of the affected Party, including, but not limited to fire, strikes, or any law, regulation or policy of any government, or any subdivision, authority or agency thereof that is enacted subsequent to the execution of this Agreement, the Party so affected, upon written notice to the other Party, shall be excused from such performance to the extent of such prevention, restriction or interference, provided that the Party so affected shall use all reasonable efforts to avoid or remove such cause or causes of nonperformance, and shall continue performance hereunder with all reasonable dispatch when such cause or causes are removed. Failure to adhere to or comply with existing laws, rules and regulations, such as but not limited to the U.S. FD&C Act and its good manufacturing practice (GMP) regulations will not be considered a Force Majeure event and will not relieve a Party of its performance obligations pursuant to this Agreement.
- **8.4 Methods of Notice**. Any notice, or other communications which are required or permitted hereunder shall be in the English language, shall be written and shall be deemed given on the date received by the receiving Party, if and when: (i) delivered personally with a signed receipt of such delivery, or (ii) sent by registered mail or certified mail, postage prepaid, return receipt requested, or (iii) sent by overnight courier with an internationally recognized courier, or (iv) sent via facsimile or electronic (e-mail) transmission, the receipt of which has been confirmed in a separate writing by the receiving Party.



8.5 Addresses for Notices. Unless and until such addresses may be changed by written notice to the other Party, complying with the terms of this Section 8.5, all notices to DREW shall be addressed to:

Drew Scientific, Inc. 4230 Shilling Way Dallas, TX 75237-1093 USA

Attention: President

Fax: 214-210-4949

Copy to: General Counsel Escalon Medical Corp. 565 E. Swedesford Road Suite 200 Wayne, PA 19087 Fax: 610-688-6830

and all notices to POINTCARE shall be addressed to:

PointCare Technologies, Inc. 181 Cedar Hill Street Marlborough, MA 01752

Attention: Petra Krauledat, Ph.D.

President & Chief Executive Officer

Fax: 1-508-281-6390

MR_BX

8.6 Governing Law: Arbitration. This Agreement shall be construed, interpreted and enforced in accordance with the substantive laws of the state of New York. Any legal action filed pursuant to and/or related to this Agreement or its interpretation shall be filed in the U.S. District Court for the Southern District of New York. The Parties shall make a good faith effort to attempt to amicably resolve any disagreements, involving their respective Presidents, before any legal action is filed by a Party to this Agreement.

Filed 02/13/2008

- Severability. If any provision of this Agreement becomes or is deemed to be invalid, 8.7 illegal or unenforceable in any jurisdiction, (a) this Agreement and the remaining provisions hereof shall continue in full force and effect and (b) the Parties shall negotiate in good faith such amendments to the provisions found to be invalid, illegal or unenforceable as are necessary to eliminate such invalidity, illegality or unenforceability.
- 8.8 No Waiver of Subsequent Breach. No waiver of any breach of this Agreement or any obligation arising under this Agreement by either Party shall constitute a waiver of any subsequent breach or breaches, whether such breaches are of a similar or dissimilar nature.
- Nature of Relationship. Unless otherwise expressly agreed upon in writing, neither Party to this Agreement shall be in any way the agent or representative of the other Party for any purpose whatsoever, and shall have no right to create or assume any obligation or responsibility of any kind, whether express or implied, in the name of or on behalf of the other Party or to bind the other Party in any manner whatsoever.
- 8.10 Reading and Understanding. Each party warrants that, prior to executing this Agreement, it carefully read the Agreement in its entirety, had the opportunity to seek legal advice, and that it understood all of the terms contained herein.
- **8.11 Counterparts**. This Agreement may be signed in counterparts, each of which shall be an original, but all of which shall be deemed to be one and the same instrument, and shall be valid and binding when so signed.

MR BX

IN WITNESS WHEREOF, this Agreement has been executed by the duly authorized officers of POINTCARE and DREW effective as of the date and year first above written.

DREW SCIENTIFIC, INC

Ву: ДМ /Д______

Name: H.M. RIMMER

Title: PRESIDENT

Date: June 2 nd 2006

POINTCARE TECHNOLOGIES, INC.

By: Mra B. Ru

vame: Petra B. Krauledat

Title: CEO

Date: June 5th, 2006

GCOPY

ist of Annexes.

List of Annexes

- Annex 1: Specifications and Development Timelines for the DREW HTc and HTw Instrumentation Platforms & the POINTCARE CD4sure™ Lymphocyte Enumeration Assay Kit
- Annex 2: Specifications and Development Timelines for the POINTCARE NP Instrumentation Platform & the reformulated POINTCARE Lymphocyte Enumeration Assay Kit
- Annex 3: Sales and Marketing Territories
- Annex 4: CD4 Lymphocyte Enumeration Assay Kit and Diagnostic Instrumentation Platform Labelling Terms & Conditions
- Annex 5: Pricing Terms and Conditions; Requirements Forecasts
- Annex 6: Warranty, Technical Support & Training

MA PBR

ANNEX 1

Specifications and Development Timelines for the DREW HTc and HTw Instrumentation Platforms & the POINTCARE CD4sure™ Lymphocyte Enumeration Assay Kit

HTw Instrumentation Platform:

- Drew is responsible for and will bear the costs associated with and related to the development and approval for sale in the United States of the HTc and HTw diagnostic instrumentation platforms that will be compatible with PointCare's CD4sure™ Lymphocyte Enumeration assay.
- Drew is responsible for and will bear all costs associated with and related to the transfer of a HT diagnostic instrumentation platforms that are compatible with PointCare's CD4sure™ Lymphocyte Enumeration Assay Kit into DREW's manufacturing organization.
- Any software problems that are detected with respect to the HTw instrumentation
 platform shall be jointly investigated. Both Parties will work cooperatively and in good
 faith to achieve consensus towards a satisfactory solution to any potential software
 issues and will establish a written process for ascertaining the equitable division of costs
 associated with the resolution of any software issue that is confirmed by both Parties.
- Development timetable attached as Attachment 1 to Annex 1
- HTw Instrumentation Platform Specifications: See Attachment 2 to Annex 1

POINTCARE CD4sure™ Assay Test Kit

- Pointcare is responsible for and will bear the costs associated with and related to the development and approval for sale in the United States of PointCare's CD4sure™ Lymphocyte Enumeration assay that will be compatible with Drew's HTc and HTw diagnostic instrumentation platforms.
- PointCare is responsible for and will bear all costs associated with and related to the development and transfer into Pointcare's manufacturing organization of a reformulated Lymphocyte Enumeration assay that shall be compatible with and operate with Drew's HTc and HTw diagnostic instrumentation platforms.
- Development timetable and POINTCARE Lymphocyte Enumeration assay kit [CD4Sure™ and the reformulated versions] Specifications: See Attachment 3 to Annex 1

MR Por

					,	,			
=	Description			Start	End	End (September South Bull British Bull	THE PERSON NAMED IN	The state of the s	44.
7	⊟Analysis and Planning .		7	2/02/2006	4/28/2006	it.	An	Analysis and Diamina	1000
<u>ر</u> بر	Comnatibility Testing		i c	John Market	2/4 5/2006	· .	1	מולמים פווח בופוווווום	
1 (1	District States		₹ ē	ozizono:	2/13/2000	41	H'KB'NB		-
, ,	Out of the second of the secon		7	2/16/2005	4/14/2006		(A) H, EK, KD	K,RD	
<u>+ 1</u>	Staffing/scheduling			3/16/2006[_	3/31/2006		国 PH,RB		****
ר ה	Product Requirements		. ,	2/16/2006	3/31/2006		PH,RB,DB	eg'	
ω_	Product Requirement Review		¥ ₩	4/04/2006	4/07/2006		[.DB.F.	[].DB,FM,PK,HR,RB,	
·.	Quality mamage		je K	3/16/2006	4/28/2006	•	DO'DW ESSE	טם'.	
ш Ж	EFeasibility of select modules		E .	3/01/2006	4/06/2006		Feasi	Teasibility of select modules	
`> 	Right angle scatter modification		¥ 3/.	3/16/2006	3/31/2006		R RB, PH, RG, DM	RG,DM	
<u>ک</u>	Test right angle scatter modification.		3/5	3/28/2006	3/29/2006		I RG.RB.PH	HdT	
<u>}</u>	Lyse mixing modification	•	× 3/C	3/01/2006	3/31/2006		0.0	•	
122	Test lyse mixing modification		7, 4/C	4/03/2006	4/06/2006	•	RADB	·	
13 m	Development of selected modules		3/	3/20/2006	6/30/2006			Development of selected modules	
14	Mixing	ı	× 4/C	4/05/2006	5/26/2006				
15	Immunogold delivery module	٠.	¥	4/12/2006	6/16/2006		THE STATE OF THE S	THE ROLL OF THE RO	
16	CD4 controls		*	4/12/2006.*	6/30/2006		25,000		
17	Fluid routing		4/6	4/05/2006.7	5/31/2006		The state of the s	HWU	
18	Optical module		4/1	4/12/2006 ×	5/31/200B		HAUTE ST		
19	Sample age extension		4/1	4/12/2006.*	6/30/2006		A STATE OF THE STA		
20	Analytical software for CD4		× 3/5	3/20/2006	6/30/2006		AD AD	An A	
21	User interface .		7 4/7		6/16/2006		Call Street	W	
22 F	Elinteoration of system	•	: F	٠	10/31/2006			and the second s	
3.	EHardware Integration		· F	3/23/2006	6/29/2006			Hardware Internation	
24	CD4 mixing module	•	3/5	3/23/2006	6/29/2006	•	TESCOLUSIES.		
25	immunogold delivery module		8	3/23/2006	6/29/2006		of the second		
18	CD4 fluid routing		, k	3/23/2006	6/29/2006		The state of the s		
27	modified optics		3/6	3/23/2006	6/29/2006		100000000000000000000000000000000000000		
- 78 -	Software Integration		Ē	3/23/2006	7/20/2006			Software Integration	
29	analytical software for CD4		× 3/2	3/23/20061*	6/29/2006				-
30	software for sample age extension		315	3/23/2006	6/29/2006	•			
31	user interface		* 3/5	3/23/2006	7/20/2006		ACTIVATED IN	SCHOOL	
32	In-house testing		, W	8/01/2006	8/31/2006		J.		- 141.0.
33	Field Testing		¥.	9/04/2006	9/29/2006				
34	Reworks		*. 8/	8/01/2006 1.1	10/31/2006			一种社会的	
35	Manufacturing engineering		16	9/01/2006	3/05/2007		, -	Manufacturing engineering	Đị.
99	Instrument manufacturing engineering		Ţ	0/02/2006	12/29/2006			ARTHUR A	
37	Reagent manufacturing engineering		* 10/C	0/02/2006 7	12/29/2006			(Agentamas)	
38	QA procedures, manuals, labelling	•		9/01/2006	-12/29/2006			(1) 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
33	Transfer to manufacturing - aggressive		12/2	2/29/2006 ^{1,7}	1/18/2007		"		
40	Transfer to manufacturing - conservative		× 1/1	1/01/2007	3/05/2007		224	- The state of the	
<u>4</u>	⊟Regulafory			1.2/01/2006	7/27/2007	•		Regulatory	tory
42	510k data and submission - aggressive		₹ 12K	2/01/2006	1/26/2007		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	35年24	,
43	510k data and submission - conservative		, 5/L	5/01/2007	7/27/2007		J.	SATISFE SE	
44	Relase to Market (non-510k)			1/05/2007	1/05/2007			. @ 1/05/2007	
45	Release to Market (510k) - aggressive		3/6	3/09/2007	3/09/2007			©3/03/2007	
46	Release to Market (510k) - conservative		711.	7/27/2007	7/27/2007		.=•	7002/120/	701
6/02/2006	5005		· 						



Attachment 2 to Annex 1

ATTACHMENT 2 TO ANNEX

	PRODUCT SPECIE	TCATIONS FO	PRODUCT SPECIFICATIONS FOR HT INSTRUMENT	
CR/BR No.	Customer or Business Requirement	PR No.	Product Requirement	Requirement Importance
CR-008-001	Parameters reported: WBC, Lym, Lym %, Mono, Mono %, Neut, Neut %, Eo, Eo %, Hgb, CD4, CD4, CD4.	PR-008-001	Instrument capable of producing 4-pt WBC differential, plus hemoglobin, plus CD4.	Mandatory φ1
CR-008-002	Additional parameters reported RBC, RDW. MCV, Hct, MCH, MCHC, Plt, MPV, PDW, Pct Baso, Baso %,	PR-008-002	Instrument capable of producing 5-part differential, plus RBC and Plt histogram. 5-part differential obtained by flow cytometer, RBC and Plt parameters obtained by impedance.	Desirable φ1 Mandatory φ2
CR-008-003	CD4 lymphocyte reportable range from 50/µL to 6,000/µL	PR-008-003	Large dynamic range of CD4 cell enumeration with precision at $200/\mu L \pm 25/\mu L$ (where $\pm 25/\mu L$ is max acceptable SD).	Mandatory ф1
CR-008-004	CD4% of total lymphocyte reportable range from 1% to 80%	PR-008-004	Large dynamic range of CD4 cell enumeration with precision at $lym > 1500/uL$ and $15\% \pm 2\%$ (where $\pm 2\%$ is max acceptable SD).	Mandatory ф1
CR-008-005	Only CD4 lymphocytes reported	PR-008-005	CD4 monocytes excluded from analysis	Mandatory $\phi 1$
CR-008-006	WBC reportable range from 500/uL to 150,000/uL	PR-008-006	Large dynamic range for WBC. Precise WBC count obtained by impedance with precision at 8,000/uL < 2%	Mandatory $\phi 1$
CR-008-007	Lym reportable range from 300/uL to 17,000/uL	PR-008-007	Large dynamic range for lymphocytes with precision at 2,000/uL < 3%	Mandatory $\phi 1$
CR-008-008	Mono reportable range from 0 to 80%	PR-008-008	Large dynamic range for monocytes with CV% at 7% is <+7% for a total WBC count > 8,000/ uL	Mandatory $\phi 1$
CR-008-009	Neut reportable range from 1 to 95%	PR-008-009	Large dynamic range for neutrophils with CV% at 60% is < 3% for a total WBC count > 8,000/ ul.	Mandatory $\phi 1$
CR-008-010	Eo reportable range from 0.1 to 90%	PR-008-010	Large dynamic range for eosinophils with CV% at 7% is <7% for a total WBC count > 8,000/ uL	Mandatory ф1
CR-008-011	Hgb reportable range from 4 g/dL to 24 g/dL	PR-008-011a	Large dynamic range for hemoglobin with precision at 7 g/dL < 2%	Mandatory ф1
		PR-008-011b	Hgb reportable range from 3 g/dL to 24 g/dL	Desirable $\phi 2$
CR-008-012	RBC reportable range from 0.02 to 9.99 M/uL	PR-008-012	Large dynamic range for RBC with CV% at 5M/uL < 1%	Desirable $\phi 1$
				Mandatory ϕ 2
CR-008-013	MCV reportable range from 40-150 fl	PR-008-013	Large dynamic range for MCV with CV% at 90 fl<1%	Desirable $\phi 1$
				Mandatory ϕ 2
CR-008-014	RDW reportable range from 10 to 25%	PR-008-014	Large dynamic range for RDW with CV% at 15% < 5%	Desirable $\phi 1$
				Mandatory ϕ 2

		Mandatory ϕ 2	at 10 fl < 5% Desirable $\phi 1$	Mandatory ϕ 2		Mandatory ϕ 2	data entry for Mandatory ϕ 1		Destrable $\phi 1$	Mandatory $\phi 1$	ssing up to 30 Desirable $\phi 1$		Mandatory Ф1	ne development Desirable φ2	e worklist. Mandatony (h)	ce to		C differential Mandatory $\phi 1$	-	munogold. Lym	munogold. Lym nce or optical	munogold. Lym ıce or optical	munogold. Lym nce or optical or CD4 Mandatory $\phi 1$	nunogold. Lym ce or optical r CD4	nunogold. Lym ce or optical r CD4 with autoloader)	nunogold. Lym ce or optical r CD4 with autoloader)	nunogold. Lym ce or optical r.CD4 with autoloader)	nunogold. Lym ce or optical r CD4 with autoloader)	nunogold. Lym ce or optical r CD4 with autoloader)	nunogold. Lym ce or optical r.CD4 with autoloader)
PRODUCT SPECIFICATIONS FOR HT INSTRUMENT	Large dynamic range for Plt with CV% at 250K/uL < 3%		Large dynamic range for MPV with CV% at 10 fl < 5%		Sample age extension for CD4 and CD4% from 8 hour age	requirement	Mitigation factors for sample age, such as data entry for	draw time, flagging for scatter plots, and training	Absolute internal control for sample age	4.5 minutes per sample	Cap piercing autoloader capable of processing up to 30	Currently etandard find eige feibes on he send	משונים מזונים מדיב נמסכים כמון סב	Expand possibilities to other sizes for future development	Choice of sequence from menu or separate worklist.	Barcode could be design to determine which sequence to	pe nsed	Two passes through flow cytometer—WBC differential	· ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` ` `	without immunogold and CD4% with immunogold. Lym	without immunogold and CD4% with immunogold. I count to be determined either by impedance or optical	without immunogold and CD4% with imm count to be determined either by impedan without gold.	without immunogold and CD4% with immunog count to be determined either by impedance or o without gold. 180 uL for CBC and an additional 45 uL for CD4	without immunogold and CD4% with imm count to be determined either by impedan without gold. 180 uL for CBC and an additional 45 uL fo Minimum 1.5mL sample volume supplied	without immunogold and CD4% with immunogold. Lym count to be determined either by impedance or optical without gold. 180 uL for CBC and an additional 45 uL for CD4 Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (with autoloader)	without immunogold and CD4% with imm count to be determined either by impedan without gold. 180 uL for CBC and an additional 45 uL for Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (Touch screen computer specified	without immunogold and CD4% with imm count to be determined either by impedan without gold. 180 uL for CBC and an additional 45 uL fo Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (Touch screen computer specified Option for security cable for computer	without immunogold and CD4% with imm count to be determined either by impedan without gold. 180 uL for CBC and an additional 45 uL fo Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (Touch screen computer specified Option for security cable for computer B&W printer specified	without immunogold and CD4% with imm count to be determined either by impedan without gold. 180 uL for CBC and an additional 45 uL fo Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (Touch screen computer specified Option for security cable for computer B&W printer specified Color printer specified	without immunogold and CD4% with immunogold count to be determined either by impedance or optic without gold. 180 uL for CBC and an additional 45 uL for CD4 Minimum 1.5mL sample volume supplied Automated cap piercing blood sampling (with autol Touch screen computer specified Option for security cable for computer B&W printer specified Color printer specified English, French, Portuguese, Spanish, Chinese, Thai,
FICATIONS FC	PR-008-015	TH 000 040	FK-008-016		PR-008-017		PR-008-018		PR-008-019	PR-008-020	PR-008-021	PR-008-022a		PR-008-022b	PR-008-023			PR-008-024					PR-008-025a	PR-008-025a PR-008-025b	PR-008-025a PR-008-025b PR-008-026	PR-008-025a PR-008-025b PR-008-026	PR-008-025a PR-008-025b PR-008-026 PR-008-027	PR-008-025a PR-008-025b PR-008-025 PR-008-027 PR-008-027 PR-008-028	PR-008-025a PR-008-025b PR-008-026 PR-008-027 PR-008-029 PR-008-029a PR-008-029a	PR-008-025a PR-008-025b PR-008-025 PR-008-027 PR-008-029 PR-008-029a PR-008-029b
TRODUCI SPEC	rit reportable range from 10-2060 K/uL	MPV remortable among face 2 25 G	Torrange range noin 2-25 m		32 hour sample age for CD4 and CD4%. 8 hours for all other parameters.	or at once parameters.	System warns user if results possibly	compromised by aged sample.	System does not report results if compromised by aged sample.	Minimum of 100 samples (including controls) in 7.5 hours	Instrument may operate for minimum of 1 hour or 30 samples unattended	Autoloader capable of handling standard tube	sizes		Choice of CBC/CD4 or CBC only			Minimum 5-pt WBC differential with CD4					Minimal sample volume used in assay							
210 000 01	- K-008-013	CB-008-016	010-000-1	2000	CR-008-017	000	C.K-008-018		C.K-008-019	CR-008-020	CR-008-021	CR-008-022			CR-008-023			CR-008-024				100 000 000	CR-008-025	CR-008-025	CR-008-025	CR-008-025 CR-008-026 CR-008-027	CR-008-025 CR-008-026 CR-008-027 CR-008-028	CR-008-025 CR-008-026 CR-008-027 CR-008-029 CR-008-029	CR-008-025 CR-008-026 CR-008-027 CR-008-028 CR-008-029	CR-008-025 CR-008-026 CR-008-027 CR-008-029 CR-008-030

MA PBK

DATE: 6/2/06 TIME: 10:02:06 AM

РРОМ: КАТНҮ 2142104950 ТО: НАЯВУ РІММЕЯ

	PRODUCT SPECIF	SICATIONS FO	PRODUCT SPECIFICATIONS FOR HT INSTRUMENT	
TR-008-031	Protected software for simple operation without	PR-008-031	Three levels of operation—service mode (through separate	Mandatory ϕ 1
4	tampering		software), supervisor mode, and limited operator mode with identity of who "logs on"	•
CR-008-032	Limited data entry	. PR-008-032	Barcoded sample and control entry	Mandatory $\phi 1$
ZR-008-033	Reagent use and expiration tracking	PR-008-033	Barcoded reagent entry and low reagent alarms	Mandatory $\phi 1$
TR-008-034	Non-editable numerical data and clusters on screen and on printouts	PR-008-034	Automated cluster gating	Mandatory $\phi 1$
CR-008-035	Automatic QC tracking of CBC and CD4 controls with control chart display	PR-008-035	Levey-Jennings control plots generated and easily printable	Mandatory $\phi1$
CR-008-036	Control material appropriate for all parameters in system	PR-008-036	Control materials including CD4 and CD4% in capped tubes with barcodes. Possibility of multiple control materials.	Mandatory $\phi 1$
CR-008-037	Data storage > 100,000 patients	PR-008-037	Appropriate data storage and hardware capability	Mandatory $\phi 1$
CR-008-038	Searchable patient history	PR-008-038	User interface designed to facilitate easy patient management	Mandatory $\phi 1$
CR-008-039	Easy daily startup and shutdown	PR-008-039a	Fully automated startup/shutdown < 5 minutes each with no customer intervention after thermal equilibrium	Mandatory $\phi 1$
		PR-008-039b	Thermal equilibrium achieved in < 30 minutes	Desirable $\phi 1$
CR-008-040	Assurance of gold reagent activity for every sample	PR-008-040	Software driven internal control for gold reagent activity	Mandatory ф1
CR-008-041	Indeterminate samples denoted by a general	PR-008-041a	Strict flag criteria for automated software gating.	Mandatory $\phi 1$
	flag symbol	PR-008-041b	Specific flag types for $\phi 2$	Mandatory ϕ 2
CR-008-042	Steady sample flow profile for analysis	PR-008-042	Flow irregularity alerts and instructions how to proceed	Desirable φ1 Mandatory φ2
CR-008-043	Instrument operation appropriate for all lab settings.	PR-008-043	External temperature operating range 16-32°C (61-90°F). Relative humidity operating range 10% - 90%, noncondensing. Bulk gold reagent bottle is expected to remain on the instrument for ≤5 days. Heater at may be needed for immunogold reaction.	Mandatory ф1
CR-008-044	Operation with all electrical sources	PR-008-044	90-250V, 47-63 Hz.	Mandatory $\phi 1$
CR-008-045	Battery backup available	PR-008-045	UPS specified with the ability to finish cycle and shutdown completely.	Mandatory ф1
CR-008-046	All preventative maintenance driven by software and performed by customer	PR-008-046	No field service or manipulation of components for preventative maintenance.	Desirable $\phi 1$

	Mandatory $\phi 1$	for CD4 Mandatory $\phi 1$	CD4 Desírable φ2	or remote Desirable $\phi 1$	future Desirable φ2	Л and Desirable ф1	Mandatory ф1	Mandatory ф1	Mandatory $\phi 1$	Mandatory ϕ 2
PRODUCT SPECIFICATIONS FOR HT INSTRUMENT	Calibration by factory, field service, or customer. Calibration only for total WBC count.	Minimum 4 months stability at room temperature for CD4 reagents	Minimum 1 year stability at room temperature for CD4 reasents	File download and instrument control capability for remote troubleshooting.	Bidirectional ASTM or equivalent acceptable with future planning for "peer to peer" file sharing.	Automated downloadable software upgrades for UI and analytical software	Field service installed	Lyophilized or desiccated bulk gold reagent bottle reconstituted by convenience package without any skilled steps by customer.	CE/UL mark for product launch	FDA 510(k) for market expansion
TICATIONS FC	PR-008-047	PR-008-048a	PR-008-048b	PR-008-049a	PR-008-049b	PR-008-050	PR-008-051	PR-008-052	PR-008-053a	PR-008-053b
PRODUCT SPECI	Automatic and manual calibration options	CD4 reagents must have minimum 2 months room temperature (4-30°C) stability upon	arrival at end user	Troubleshooting done with minimal service		Software upgrades performed by customer	Installation performed without experienced	_ 	Instrument conforms to international regulatory	standards
•	BR-008-001	BR-008-002		BR-008-003	, and the second	BR-008-004	BR-008-005	BR-008-006	BR-008-007	

END OF DOCUMENT

Attachment 3 to Annex I

ATTACHMENT 3 TO ANNEX 1

Synopsis of PointCare Technologies Assay for the Identification of CD4 Positive Lymphocytes:

Expression as Percentage of Lymphocyte Count ("CD4%") and CD4 Lymphocyte Count ("CD4 Absolute")

(Two-Page Document)

SAMPLE

- Sample is 45μl of whole blood in EDTA.
- 2. Cells must be suspended according to standard hematology practice.
- 3. Proceed to sample immunolabeling

SAMPLE IMMUNOLABELING

- Add 45µl whole blood to 20µl PointCare CD4 immunogold and 45µl of PointCare accelerant. The order in which these reagents are combined is not important,
- Mix by "vortex" action at approximately 1700 rpm or by similar method for approximately 5 seconds.
- Depending on efficiency of mixing method, incubation at 37C may be required up to 180 seconds.
- 4. Proceed to sample lysing.

SAMPLE LYSING

- 1. Add $300\mu I$ Erythrolyse II (Beckman Coulter) to the blood/gold/accelerant mixture to Initiate red cell lysis.
- Mix by "vortex" action at 1700 rpm for 10 seconds. In contrast to Step 2 in "Sample Immunolabeling", these conditions are critical, and if alternative mixing is used, the effect must mimic the effect of "vortexing".
- 3. Immediately add 133µl of Stabliyse (Beckman Coulter) to stop red cell lysis.
- 4. Mix by "vortex" action at 1700 rpm for 10 seconds. Again, in contrast to Step 2 in "Sample immunolabeling", these conditions are critical, and if alternative mixing or timing is used, the effect must mimic the effect of "immediate addition" and "vortexing".
- Sample is now stable and Isotonic diluent can be added if required for fluid handling by instrumentation system.
- 6. Proceed to Optical Cytometer Analysis.

OPTICAL CYTOMETER ANALYSIS

- Optical cytometer must clearly distinguish lymphocytes from monocytes as both cell types carry CD4 antigens.
- CD4+ versus CD4- lymphocyte discrimination is performed using the parameter commonly termed "Side Scatter" in flow cytometry. Discrimination improves, as "Back Scatter" collection angles are included.

MIR BR

D.

COMPUTATION OF CD4 "Percent" AND CD4 "Count"

- Make the <u>CD4 Percent</u> computation from the Optical Cytometer analysis by counting events in the CD4+ lymphocyte cluster and dividing by the total number of CD4+ and CD4- lymphocyte events in both optically determined clusters.
- 2. Make the <u>CD4 Count</u> computation by multiplying the CD4 Percent (expressed as a decimal fraction) from the Optical Cytometer by the lymphocyte count obtained by impedance, or other non-optical, counting of the same sample.

FLUID VOLUME TOLERANCES

Reagent	Optimal Volume (µl)	Volume Range Allowed
Whole blood	45	±10%
Accelerant	45 .	±30%
Immunogold	20	±30%
Erythrolyse II	300	±10%
Stabilyse	133	±10%

END

MUR BK

RA

Annex 2

Specifications and Development Timelines for the NP Instrumentation Platform & the reformulated POINTCARE Lymphocyte Enumeration Assay Kit

NP Diagnostic Instrumentation Platform:

Pointcare to negotiate a Development and Manufacturing Agreement with C2 or another third party manufacturer that incorporates the specifications and development timetables included in *Attachment 1* to *Annex 2* (Near Patient Instrument for Developing World Market, by D. Barry, May 4, 2006).

POINTCARE CD4sure™ Assay Test Kit

- Pointcare is responsible for and will bear the costs associated with and related to the development and approval for sale in the United States of PointCare's Reformulated CD4sure™ Lymphocyte Enumeration assay that will be compatible with the NP diagnostic instrumentation platform and, as appropriate, Drew's HTc and HTw diagnostic instrumentation platforms.
- PointCare is responsible for and will bear all costs associated with and related to the development and transfer into Pointcare's manufacturing organization of a reformulated Lymphocyte Enumeration assay that shall be compatible with and operate with the NP diagnostic instrumentation platform and, as appropriate, Drew's HTc and HTw diagnostic instrumentation platforms.
- Development timetable and Product Specifications are attached hereto as Attachment
 2 to Annex 2 and incorporated by reference (<u>TO BE DELIVERED BY POINTCARE BY JUNE 30, 2006 AND AGREED UPON BY THE PARTIES BY JULY 30, 2006).</u>



Attachment 1
to Annex 2:

FROM: KATHY 2142104950 To: HARRY RIMMER

DATE: 6/2/06 TIME: 10:02:06 AM

PAGE 8 OIDAD

	PointCare Technologles Inc.	CUSTOMER, BUSINESS AND PRODUCT REQUIREMENT SPECIFICATIONS	Document No.: CBPR-007	Rev. A
E	ffective Date:	TITLE: NEAR PATIENT SYSTEM FOR	Page: 1 of 6	
I	DRAFT	DEVELOPING WORLD MARKET		

Attachment 1 to Annex 2

Title of Program:

Near Patient Instrument for Developing World Market

Date:

May 4, 2006

Author:

Don Barry

1. Purpose and Scope

This document describes the customer and business requirements for the Near Patient System and the translation into product requirements. This system is to be co-developed by PointCare Technologies and a third party. The design controls for this project will be maintained separately by PointCare Technologies and the third party per their respective design control system.

2. Product Overview

The Near Patient System is a flow-based and impedance-based system that will allow for analysis of CD4, CD4%, and certain hematology parameters to economically manage monitoring of HIV Antiretroviral Therapy. Designed for smaller clinics and remote testing venues, the system will support small patient sample volumes. It is comprised of the Near Patient Instrument and its associated reagents.

3. Customer, Business and Product Requirements

The following requirements will ensure development of the above described Near Patient System.



PAGE 9 OID

FROM: KATHY 2142104950 To: HARRY RIMMER

DATE: 6/2/06 TIME: 10:02:06 AM

		DEVELOPING WORLD MARKET	DRAFT
······································	Page: 2 of 6	TITLE: NEAR PATIENT SYSTEM FOR	Effective Date:
Rev. A	Document No.: CBPR-007	CUSTOMER, BUSINESS AND PRODUCT Document No.: REQUIREMENT SPECIFICATIONS CBPR-007	PointCare Technologies Inc.

CR-007-011 CR-007-012	CR-007-01	CR-007-01	CR-00/-01	- CD-02-01	בש המא	CR-007-009	CR-007-008	CR-007-007	CR-007-006	CK-007-002	200 Z00 Q	CR-007-004	CR-007-003	CR-007-002		CR-007-001	CR/BR No.
compromised by agen sample.		parameters.	CD4%. Minimum 8 hours for all other		0 Hemoglobin reportable range from 0.5 g/dL to	9 Eosmophil reportable range from 0.1 to 90%	8 Neutrophil reportable range from 1 to 95%	7 Monocyte reportable range from 0 to 80%	6 Lymphocyte reportable range from 1 to 95%	100,000/uL	-		3 CD4% of total lymphocyte reportable range from 1% to 80%.	CD4 lymphocyte reportable range from 50/uL to 6,000/uL	ļ	Parameters reported: WBC, Lym, Lym %,	Customer or Business Requirement
	PR-007-012		110-700-111		PR-007-010	PR-007-009	PR-007-008	PR-007-007	PR-007-006	. Tre 00/ 000	PR-007-005	PR-007-004	PR-007-003	PR-007-002		PR-007-001	PR No.
100 0	Mitigation factors for sample age, such as data entry for draw time. flagging for dot plots, and training		minimum age requirement.	12 g/dL < 1.5% CV	Large dynamic range for hemoglobin with precision at	Large dynamic range for eosinophils with precision at $5\% < 10\%$ CV	Large dynamic range for neutrophils with precision at $50\% < 4\%$ CV	Large dynamic range for monocytes with precision at 7% < 10% CV	Large dynamic range for lymphocytes with precision at 15% < 5% CV	obtained by impedance at 6,000/uL < 2.5% CV	Targe dimamic range for WRC Procise WRC count	CD4 monocytes excluded from analysis	Large dynamic range of CD4 cell enumeration with precision at 15% < 10% CV	Large dynamic range of CD4 cell enumeration with precision at 200/uL < 10% CV.	differential, plus hemoglobin, plus CD4.	Instrument capable of producing WBC and a 4-pt WBC	Product Requirement
	Mandatory		wandany		Mandatory	Mandatory	Mandatory	Mandatory	Mandatory	reminatory	Mandatory	Mandatory	Mandatory	Mandatory		Mandatory	Requirement Importance



MUR PK

PAGE	40	-1-		7
PAGE	10	UIT	וגו	d

	CR-007-028 Da	CR-007-027 At	CR-007-026 Ni	CR-007-025 Mi	-	CR-007-023 Li		CR-007-022 Pr		CR-007-021 Lo	CR-007-020 - Pri	CR-007-019 Us	CR-007-018 Ke	CR-007-017 No			CR-007-016 WI	CR-007-015 Min	CR-007-014 Dai	Effective Date: DRAFT		PointCare Technologies Inc.	
Searchable patient history	Data storage > 100,000 patient results	Automatic QC tracking of controls with control chart display	Numerical data output with no visual interpretation	Minimal reagent waste	Reagent use and expiration tracking	Limited data entry	without tampering	Protected software for simple operation	•	Local languages aväilable for each market	Printable results	Use of instrument in outdoor setting	Keypad with integrated computer operation	No handling of open blood tubes	C	CD4 gold reagent	WBC differential not to be compromised by	Minimal cycle time to allow for reruns when necessary	Daily throughput appropriate for Near Patient market	DEVELOPING WORLD MARKET	מחווי ה. אוני אים א יחובאויף פעפיוניא	CUSTOMER, BUSINESS AND PRODUCT REQUIREMENT SPECIFICATIONS	
PR-007-029	PR-007-028	PR-007-027	PR-007-026	PR-007-025	PR-007-024	PR-007-023		PR-007-022		PR-007-021	PR-007-020	PR-007-019	PR-007-018	PR-007-017			PR-007-016	PR-007-015	PR-007-014		_		1.
User interface on external of	1000 patient results available on instrument. Expandable data storage by optional external USB ke and external computer. Can be post launch upgrade.	Levey-Jennings control plots generated and easily printable. Can be post launch upgrade.	Automated cluster gating	Attention to small fluid volume usage	RF ID or barcode for reagent use tracking	RFID or barcode sample and control entry	mode, and limited operator mode	Three levels of operation—service mode, supervisor	upgrade,	English, French, Portuguese, Spanish, Chinese, Thai, Vietnamese, and Russian screens. Can be post launch	Printer to be specified by instrument manufacturer	Screen readable in full sunlight	Keypad and integrated computer design	Automated cap piercing blood sampling from manually introduced sample tubes (no autobader)	another pass to obtain CD4	pass to obtain WBC differential without immunogold,	Two passes through optical	<5 minute cycle time	Minimum of 50 samples plu	H B GG. O. O.	Page 3 of 6	Document No.: Rev. A CBPR-007	
User interface on external computer designed to	1000 patient results available on instrument. Expandable data storage by optional external USB key and external computer. Can be post launch upgrade.	ots generated and easily		ilume usage	nt use tracking	nd control entry	r mode	service mode, supervisor	in in it is	e, Spanish, Chinese, Thai, creens. Can be post launch	nstrument manufacturer	light .	nputer design	ood sampling from ile tubes (no autoloader)	1% with immunogold.	ntial without immunogold,	l analysis chamber — one		us controls in 7.5 hours			7. A	

Mandatory
Desirable
Mandatory
Desirable

Mandatory

Mandatory

Mandatory

Mandatory

MA TBK

Mandatory Mandatory

Desirable

Desirable

Mandatory Mandatory

Mandatory

PAGE 1 OIDAD

			 - -		
P _C	PointCare Technologies Inc	CUSTOMER, BUSINESS AND PRODUCT REQUIREMENT SPECIFICATIONS		Document No.: CBPR-007	Rev. A
Effective Date: DRAFT	Date:	TITLE: NEAR PATIENT SYSTEM FOR DEVELOPING WORLD MARKET		Page: 4 of 6.	
<u></u>	CR-007-030	Easy daily startup and shutdown	PR-007-030	Fully automated starts	Fully automated startup/shuidown <5 minutes each
		,		with no customer intervention	vention
_	CR-007-031	Assurance of gold reagent activity for every	PR-007-031	Software driven internal	al control for gold reagent
1		sample		activity by monitoring monocytes.	monocytes.
	CR-007-032	Indeterminate samples denoted by a general	PR-007-032	Strict flag criteria for a	Strict flag criteria for automated software gating. Flag
		пад зупью:		mode.	explanation available in administration and service mode.
	CR-007-033	Instrument operation appropriate for all lab	PR-007-033	External temperature	External temperature operating range 18-34°C (64-
and Theorem		settings.		93°F). Relative humid 32°C, non-condensing	93°F). Relative humidity operating range 10% - 80% at 32°C, non-condensing. A thermoelectric cooler for
				gold reagent bottle may need to be added.	y need to be added.
	CR-007-034	Ability to operate in and regions with airborne dust	PR-007-034.	Protected mixing chan electronics	Protected mixing chambers, optical assembly, and electronics
	CR-007-035	Tamper proof operation of instrument	PR-007-035	Door and cover sensoi	Door and cover sensors to prevent operation when
1			-	open	4
	CR-007-036	Multiple use gold reagent bottle	PR-007-036	Lyophilized or desicca	Lyophilized or desiccated bulk gold reagent bottle
				convenience package i	convenience package is an alternative if instrument
1				reconstitution is not feasible.	asīble.
T_	CR-007-037	Container available for easy transport	PR-007-037	Weight < 50 lbs in approved container	roved container
	CR-007-037	Instrument can be moved by customer	PR-007-038	Durable hardware cap	Durable hardware capable of shock/vibration
		without service call.		resistance. No optical	resistance. No optical/mechanical adjustment after
	200			transportation in approved container.	oved container.
.T.	CK-007-039	onian toothamic	FK-00/-039	51Ze < 35 cm x 25 cm x 34	34 cm
	CK-007-040	Ability to participate in proliciency programs.	PK-007-040	Can be post launch up	Can be post launch upgrade. Requires collaboration
	**************************************			make proficiency sam	make proficiency samples compatible with light scatter
<u>.</u> T	170 Zulo a.	Operation with all clocking assumed	ממן מער	based system.	
	T#0_700_21	ореганоп мин аменения som ces	T#0-/00/-0#1	90-250V, 47-63 Hz, all	90-250 V, 47-53 Hz, all commonly used connectors

Mandatory

Mandatory

Mandatory

Mandatory



Mandatory

Desirable Desirable Mandatory

Mandatory

Mandatory

Mandatory

Desirable

PAGE 2 OID

FROM: KATHY 2142104950 To: HARRY RIMMER

BR-007-010

Instrument conforms to international

PR-007-054

CE/UL mark for product launch. FDA 510(k) for

Mandatory

Mandatory Mandatory Mandatory

Mandatory

Mandatory

Mandatory

Mandatory

market expansion.

regulatory standards

DATE: 6/2/06 TIME: 10:02:06 AM

_			BR-007-009 Multiple use gold reagent bottle	BR-007-008 Installation performed by field service	BR-007-007 Software upgrades p	visits one-for-pic-	-	4-	BR-007-004 Allow only PointCare reagents to be used	arrival		BR-007-003 All reagents must ha	•	BR-007-002 Minimize lab space		BR-007-001 No calibration done by customer		customer.	CR-007-044 All preventative main		CR-007-043 Battery backup available		CR-007-042 Capability to operate		Effective Date: TITLE: NI	REQUIK			
			•		Software upgrades performed by customer P.	visits unit with minimal service 1.	al comico				-30°C) stability upon	All reagents must have minimum 2 months		PI					All preventative maintenance performed by PF			lar power).	Capability to operate from alternative energy PR	DEVELOPING WORLD MARKET	TITLE: NEAR PATIENT SYSTEM FOR	REQUIREMENT SPECIFICATIONS	CUSTOMER, BUSINESS AND PRODUCT		
			PR-007-053	PR-007-052	PR-007-051	18,007,000	030-200-84 6#0-700-81	טיט ביטט נד	PR-007-048			PR-007-047		PR-007-046		PR-007-045			PR-007-044		PR-007-043		PR-007-042	끔		NS			
on average customer usage.	Potentially several sizes will be necessary dependent	multiple uses within open vial stability limits.	Lyophilized or desiccated gold reagent bottle for	Field service or distributor installed	Automated downloadable software upgrades	тие иоминан сервонну тол темпое поправлючив.	File download carefullier by cyantue-nee reagent		RFID or barcode encryption to prevent counterfeit reagents			Minimum 4 months stability at 30°C.	contained and handled on board of instrument	Diluent, lyse, clean, gold, and accelerant reagents	installer.	Calibration by factory with possible adjustment by	instructions.	maintenance done by customer guided by on screen	Manipulation of components for preventative	shutdown completely.	UPS specified with the ability to finish cycle and	manufacturer. Can be post launch upgrade.	Line conditioning to be specified by instrument		Page: 5 of 6 .	CBFR-00/	Document No.: Kev. A	· ·	

Mandatory

Mandatory

Desirable

Mandatory

Mandatory

Page 15 of 35

DRAFT

Effective Date:

PAGE 3 OIDAD

PointCare
Technologies Inc.

CUSTOMER, BUSINESS AND PRODUCT

Rev. A

FROMI KATHY 2142104950 TO: HARRY RIMMER

DATE: 6/2/06 TIME: 10:02:06 AM

TITLE: NEAR PATIENT SYSTEM FOR REQUIREMENT SPECIFICATIONS DEVELOPING WORLD MARKET END OF DOCUMENT Document No.: CBPR-007 Page: 6 of 6

Attachment 2 to Annex 2

Annex 3 Sales & Marketing Territories

The Parties agree as follows;

- DREW will have non-exclusive worldwide rights to market and sell the HTc platform and the NP platform and the respective CD4 lymphocyte enumeration test kits under the DREW label. POINTCARE will have non-exclusive worldwide rights to market and sell the HTw platform and the corresponding CD4 lymphocyte enumeration kit under the POINTCARE label. POINTCARE will have non-exclusive worldwide rights to market and sell the NP platform and the corresponding CD4 lymphocyte enumeration kit under the POINTCARE label as well as other labels, one of which may be the Beckman Coulter label.
- Notwithstanding the above, the Parties agree that each company will lead the
 marketing and sales effort in certain territories (the "Market Leader") while the
 other company will support the Market Leader's efforts in such territory (the
 "Supporter").
- The Market Leader shall have the right and responsibility to develop a distribution and customer service capability in a defined territory. The Market Leader shall not only diligently promote the products offered under its own label but also offer the products under the Supporter's label whenever applicable and not competitive to the Market Leader's product. The Supporter shall promptly refer all sales leads from the Market Leader's territories to the Market Leader. The Market Leader shall diligently pursue such sales leads and report progress on a regular basis to the Supporter. The Market Leader agrees to sell and service the Supporter's products within its territories; to the extent it is reasonably able. The Supporter shall promptly provide, upon request from the Market Leader, product information, testimonials from opinion leaders, references from customers and any other supporting information that is requested. The Market Leader will bear all costs related to the marketing and sales effort in its respective territories, including the reimbursement of all reasonable expenses incurred by the Supporter. Only expenses that have been pre-approved by the Market Leader shall be reimbursable.



- The Market Leader shall propose a "Sales Plan" for each territory for which it is responsible which shall detail the distribution channels, customer support facilities, pricing, target sales volumes and any other relevant information. The Parties shall discuss the Sales Plan and the Market Leader shall incorporate any reasonable input and suggestions from the Supporter. Progress shall be reviewed against such Sales Plan.
- The Market Leader shall retain its rights and responsibilities in a territory for an initial 18 months from the date of product introduction in said territory. During this period the Parties will review progress against the Sales Plan every six months. After the initial 18 months, the Market Leader shall retain its position for additional 12 month periods if the Sales Plan was fulfilled or exceeded. Should the Supporter have an agreement with a distributor that commits to selling at least 50% more instruments during a twelve (12) month period than the commitment of the Market Leader, and the Supporter's distributor issues a non-cancellable purchase order for twenty-five (25) percent of the twelve month sales commitment, the Supporter shall have the right to initiate its own sales and service efforts in sald territory.
- Should a Party to this Agreement or its authorized agent obtain a Purchase Order from a Non-Government Organization ('NGO'), or a similar organization that is located within a territory in which the other Party is the Market Leader, the Market Leader and/or its authorized agent(s) shall support the installation, servicing and reagent supply for the instruments sold to the NGO or similar organization within its territories. The Market Leader or its authorized agent(s), at the direction of the Market Leader, shall be compensated at its respective standard rates for such services. Such a Purchase Order will not entitle the Party securing such a Purchase Order to otherwise market in the territory of the Market Leader unless otherwise permitted by this Agreement.
- "Product Introduction" shall be defined as the point in time when the Market Leader formally offers the product for sale and is accepting purchase orders. The Market Leader must offer product for sale at least two (2) months before the product is available and can be legally sold or distributed within the territory. At all times and in all territories within its scope of responsibility, the Market Leader shall make best efforts to fulfil all necessary duties to prepare for product distribution and sale within its territories and as agreed upon as

- quickly as is commercially reasonable, including but not limited to achieving compliance with applicable laws and regulations. If the Market Leader unreasonably delays the Product Introduction into a territory, the Supporter shall have the right to initiate its own sales and service efforts in that territory.
- DREW will be the Market Leader in the following territories at the time of initial Product Introduction: USA, Russia, China, The European Union, Philippines, Hong Kong, Taiwan, Thailand, Malaysia, Vietnam, Korea, Egypt, Pakistan, Bangladesh, and Turkey.
- POINTCARE will be the Market Leader in the following territories at the time of initial Product Introduction: Canada, Sub-Saharan Africa, Central America and the Caribbean Island Nations.
- Both Parties will independently sell and market products under their own label in India.
- From time to time, both Parties shall discuss territories not covered at the time of the Agreement. Both Parties shall make reasonable efforts to begin distribution in territories not covered at the time of the Agreement. At any time during the Agreement, either Party shall have the right to propose Market Leadership in a new territory. If a Sales Plan is proposed that can not be significantly exceeded by the other Party, the proposing Party shall have the right to assume the Market Leader position.
- With respect to Trade Shows and other exhibit and sales presentation venues, it is acknowledged that each Party shall attend certain Trade Shows and public events ("Shows") where it will seek to merchandise the products covered under this Agreement. To provide efficient coverage of such Shows and minimize redundancies and sales presentation overlap, it is agreed that DREW will attend those Shows that are related to clinical diagnostics, as well as regional distributor Shows within its Territories. POINTCARE shall be responsible for attending Shows that are specifically related to HIV treatment. While each company shall bear its own costs associated with attending and/or participating in a Show, the Parties also agree that they will provide reasonable support to each other, as requested during such Shows, including but not limited to the provision of appropriate personnel, instrumentation, assay/reagent kits, and scientific and marketing literature. The Parties further



agree that by the fifth (5th) day of the fourth calendar quarter of every year, they will submit to each other a list of the Shows which they propose to attend in the coming year. The Parties will then discuss these proposals and work cooperatively to allocate needed personnel and resources to support the proposed programs. It is recognized that additional Shows may be added to the schedule of a Party during the course of the calendar year. Each Party will make a best effort to provide at least sixty (60) days notice of the scheduling of an additional Show. The notified Party will make a best effort to provide any needed support should such timely notice be received. If less than sixty (60) days of notice is provided, the receiving Party is under no obligation to assist but should make as reasonable an effort as possible to assist.

• The Parties agree to work cooperatively to develop a brochure and CD presentation that can be used to communicate the benefits of using the HTc, HTw and NP diagnostic instrumentation platforms and CD4 Lymphocyte Enumeration assay kits developed under this Agreement. The Parties shall jointly agree upon and equally share all costs associated with such a brochure and CD presentation development effort. The Parties will work cooperatively to develop a budget, as well as a concept that can be jointly utilized by the Parties in their respective territories.

MR BK

Annex 4 Product Labelling Terms & Conditions

The Parties agree as follows:

- Drew shall have the right to market and sell the HTc and NP diagnostic instrumentation platforms and the CD4 Lymphocyte Enumeration assay kits under its own labelling.
- POINTCARE shall have the right to market and sell the HTw and NP diagnostic instrumentation platforms and the CD4 Lymphocyte Enumeration assay kits under its own labelling.
- Each Party agrees to assist the other Party and to cooperate as reasonably necessary, granting any licenses that are required, in order that each Party can, if it chooses, market and sell the above noted products under its own brand and with its own labelling. However, it is acknowledged that if DREW deviates from any labelling recommendations made by POINTCARE with respect to its NP diagnostic instrumentation platform or CD4 Lymphocyte Enumeration assay kits and/or if POINTCARE would deviate from the labelling recommendations of DREW relative to DREW'S HTw diagnostic instrumentation platforms, the Party that chooses to modify the labelling assumes the full risk and responsibility for any damages, injuries, regulatory and/or any other actions that may result and hereby agrees to fully defend and indemnify the other Party against any and all resulting claims or legal actions, threatened or actual.
- Subject to the liability disclaimers included in this Agreement, including but not limited to this *Annex 4*, POINTCARE shall package its NP instrumentation platform and CD4 Lymphocyte Assay kits which are ordered for purchase by DREW in accordance with the labelling specifications provided to POINTCARE by DREW.
- Subject to the liability disclaimers included in this Agreement, including but not limited to this Annex 4, DREW shall package its HTw diagnostic instrumentation platforms which are ordered for purchase by POINTCARE in

MIR BK

- accordance with the labelling specifications provided to DREW by POINTCARE.
- DREW agrees to provide reasonable cooperation to POINTCARE should POINTCARE request that labelling requirements of a POINTCARE customer be included on any HTw diagnostic instrumentation platform that DREW manufacturers for sale to POINTCARE. POINTCARE agrees to accept and pay any and all reasonable and documented costs for such modifications and to provide DREW with full defense and indemnity for any and all resulting claims or legal actions, threatened or actual, that may result from the labelling change(s) requested by POINTCARE.

MR PBK

Annex 5 Pricing Terms & Conditions; Requirements Forecasts

- DREW agrees to sell HTw diagnostic instrumentation platforms to POINTCARE that are labelled in accordance with POINTCARE'S specifications at a price that shall not exceed USD \$23,700. Further, DREW agrees to sell HTw diagnostic instrumentation platform spare/replacement parts and accessories to POINTCARE, in quantities that are sufficient to meet its requirements, at a discount of forty-five (45) percent off of the current published list price. The spare parts list is attached hereto as Attachment 1 to Annex 5. DREW shall provide POINTCARE with its experience and assistance in ascertaining the type and quantity of spare/replacement parts and accessories that POINTCARE should consider maintaining in its inventory. Further, in order that POINTCARE is able to develop a system of "loaner" diagnostic platforms that it can provide to its customers and end-users to temporarily replace platforms that are under repair, DREW will also allow POINTCARE to purchase one HTw diagnostic instrumentation platform at DREW'S standard cost for every ten (10) HTw diagnostic instrumentation platforms purchased by POINTCARE
- POINTCARE agrees to sell NP diagnostic instrumentation platforms to DREW that are labelled in accordance with DREW'S specifications at a price that shall not exceed USD \$ 14,000 . Further, POINTCARE agrees to sell spare/replacement parts and accessories to DREW, in quantities that are sufficient to meet its requirements, at a discount of forty-five (45) percent off of the current published list price (price list will be supplied). POINTCARE shall provide DREW with its experience and assistance in ascertain the type and quantity of spare/replacement parts and accessories that DREW should consider maintaining in its inventory. Further, in order that DREW is able to develop a system of "loaner" diagnostic platforms that it can provide to its customers and end-users to temporarily replace platforms that are under repair, POINTCARE will also allow DREW to purchase one NP diagnostic instrumentation platform at POINTCARE'S standard cost for every ten (10) NP diagnostic instrumentation platforms purchased by DREW.



- POINTCARE also agrees to sell CD4 Lymphocyte Enumeration Assay Kits for use on the HTc platform to DREW that are labelled in accordance with DREW'S specifications according to the following price schedule:
 - o Cost of \$4.00 per test for total sales volumes of up to 500,000 CD4 tests per year, based upon the relevant Anniversary Date.
 - Cost of \$3.50 per test for total sales volume between 500,001 and 1
 million CD4 tests per year, based upon the relevant Anniversary Date
 - Cost of \$3.00 per test for total sales volume above 1 million tests per year, based upon the relevant Anniversary Date
- POINTCARE agrees to sell CD4 Lymphocyte Enumeration Kits for use on the NP platform to DREW that are labelled in accordance with DREW's specifications according to the following pricing schedule. Should DREW experience price erosion averaging twenty-five percent (25%) or more within its Territories, on average, using average revenue per test as the measure during any twelve month period, as compared to the average revenue per test during the initial twelve month period of sales, the Parties agree to renegotiate the pricing terms for the assay tests (kits) on a good faith basis.
 - Cost of \$4.00 per test for sales volumes of up to 1 million CD4 tests per year, based upon the relevant Anniversary Date.
 - o Cost of \$3.50 per test for sales volumes of up to 3 million CD4 tests per year based upon the relevant Anniversary Date.
 - Cost of \$3.00 per test for sales volumes above 3 million CD4 tests per year based upon the relevant Anniversary Date.
- POINTCARE agrees to pay DREW USD \$ 0.30 per CD4 Lymphocyte
 Enumeration test that POINTCARE sells for use on a DREW manufactured
 HTw diagnostic instrumentation platform.
- It is understood that each CD4 Lymphocyte Enumeration Assay Kit may contain more than one test per kit, and that the pricing noted in this *Annex* is per test, not per assay kit.

MIR BOX

Filed 02/13/2008

- The Parties will provide each other with rolling twelve (12) month forecasts of their purchase requirements. The first month of the initial forecast shall be considered a firm commitment to purchase. Seventy (70) % of the second month forecast that was included in the initial forecast shall also be considered a firm purchase commitment. The remaining ten (10) months of the initial forecast are considered to be for planning purposes only. However, each Party is required to provide their rolling forecast to the other Party by the fifteenth (15th) day of every month and one hundred (100) % of said forecast for the following month shall be considered a firm purchase commitment. No less than seventy (70) % of the following month's forecast shall also be considered a firm purchase commitment. [Example - On May, 14, 2007, POINTCARE issues an updated "rolling" 12 month forecast that includes an order for 10 HTw units in June, 2007 and 10 HTw units in July, 2007. Pointcare would be committed to purchase at least 10 units in June and at least 7 units in July.].
- The Parties agree that payment for any purchases made under this Agreement shall be delivered to the other Party within forty-five (45) days of receipt of the invoice. No invoices will be issued by either Party before delivery of goods. Notwithstanding the above, DREW will agree to allow POINTCARE to extend the payment term to sixty (60) days, rather than forty-five (45) days, for the initial six (6) month period commencing when POINTCARE receives the first invoice from DREW for the HTw platform.
- Insurance: Both Parties agree to maintain the following insurance coverages:
 - Products Liability Coverage: Minimum amount of USD \$1,000.000.00 per occurrence and USD \$3,000,000.00 in the aggregate.
 - General Liability Insurance: Minimum amount of USD \$1,000.000.00 per occurrence and USD \$2,000,000.00 in the aggregate.

MAK BK

Attachment I to Annex 5

ATTACHMENT 1 TO ANNEX 5

	Excell22 Parts Price List May 2006			•
PN	Description		06 list	45% discount
FN	Description		US\$	price US\$
EDI 1-2705-019	Low Vacuum Reservoir Assy. w/bracket	ea.	392.65	215.95
FRI I-2705-020	TUBING, TYGON, 1/16ID, Red 50 ft roll	ft	26.84	14.76
FRU-2705-021	TUBING, TYGON, 1/8ID, 1/16W 50 ft roll	ft	100.27	55.15
FRU-2705-022	TUBING, TYGON, 1/32ID, 1/32W 50 ft roll	ft	25,36	13.95
FRU-2705-023	TUBING, TYGON, 1/16ID, 1/8OD 50 ft roll	ft	29.43	16,18
FRU-2705-024	TUBING SILASTIC .062 50 ft roll	ft	197.51	108.63
FRU-2705-026	TUBING, TYGON, MICRO, .060 X 0.020 50 ft roll	in	66.99	36.84
FRU-2705-027	TUBING, TYGON, 5/32 X 3/32 50 ft roll	ft	64.68	35.57
FRU-2705-028	TUBING, TYGON 5/16 X 3/16 10 ft roll	ft	46.86	25.77
FRU-2705-029	TUBING, TYGON 1/8 ID, Red 50 ft roll	ft .	98.18	54.00
FRU-2705-031	TUBING, TYGON .04ID X .13OD 100 ft roll	ft	215.60	118.58
FRU-8100-005	WBC Aperture Assy.	ea.	166.93	91.81
FRU-8400-005	Pressure Reservoir Assy.	ea.	287.93	158.36
	Valve, 12V, 2W, 1/16 port	ea.	233,67	128.52
	Valve, 12V, 3W, 1/8 port	ea.	243.51	133.93
FRU-8400-010	Valve, 12V, 2W, 1/8 port, Membrane	ea,	254.79	140.13
FRU-8400-013	Valve, 12V, Pinch Valve Normally Open	ea.	213.29	117.31
FRU-8400-018	Valve, 9V, 3W, 5/32 port, Red Leads	ea.	404.16	222,29
	Valve, 12V, 3W, Manifold Mtd.	ea.	296.67	163.17
	Valve, 12V, 2W, Manifold (round)	ea,	365.42	200,98
FRU-8400-026	Valve, 12V, 3W, Manifold, Coll (square)	ea.	288.20	158.51
	RED indicator Lamp, pkg of 2	ea.	34.87	19.18
	WHITE indicator Lamp, pkg of 2	ea.	34.87	. 19.18
FRU-8400-038	3/32" x 2" O-Ring, 10" Reservoirs Pkg of 5	ea.	15.00	8.25
FRU-8400-039	3/32 X 2.5" O-Ring-5PSI Reservoir, Waste Jar Pkg of 5	ea.	15.00	8.25
FRU-8400-045	Wave Spring Washer, HGB Systems Pkg of 10	ea.	15.00	8.25
FRU-8400-046	FILTER, FLUID, 25MM DIA. Pkg of 5	ea.	64.90	35,70
FRU-8400-055	540 NM OPT BANDPASS FILTER	ea,	105.57	58.06
FRU-8400-059	WESCOR Check Valve Pkg of 5	ea.	29.65	16.30
FRU-8400-070	Valve, 12V, 2 Way, 1/16 Port, Wet Sleeve, EPDM Seal (sheath)	ea.	211.04	116.07
FRU-8400-073	Clamp, 1 Ear w /Liner, new Guard Block Pkg of 10	ea.	20.00	11.00
FRU-8400-079	Metering Tube, 3.5" Lg	ea.	61.77	33,97
FRU-8400-130	Paint, Touch Up, Drew Ash Gray	ea,	28.74	15.81
FRU-8400-131	Paint, Touch Up, Drew Green	ea.	52.25	28.74
FRU-8516-004	Delay Line assy., (Silencer)	ea.	640.15	352.08
FRU-8516-005	RBC Aperture Excell, AL 8X8, 3000 Excell 22	ea.	184.86	101.67
FRU-8516-010	WBC Transducer Excell Series	ea.	305.64	168.10
FRU-8516-025	"O" ring Kit, Apertures Excell, AL 8X8, ATAC, 3000	ea.	69.58	38.27
FRU-8516-030	Needle Assy., W/Nut & O-ring (New Style)	ea.	327.58	180.17
FRU-8516-059	Guard Block Assy Modification Klt	ea.	84.87	46.68
	HGB LED REPLACEMENT KIT	ea.	101.97	
	Dual Metering Tube Board, Excell Series	ea.	321.09	176.60
	O_RING 2mm X 4mm Pkg of 10	ea.	20,00	11.00
FRU-8516-084	Battery, Lithium, 3V, Coin	ea,	15.00	8.25
FRU-8516-087	Check Valve, 1/8" In Line, Hi Flow Pkg of 5	ea.	30.25	16.64 29.81
	Electronic Potentiometer, Z-3 Pkg of 4	ea.	54.21	96.50
	Sensor, Pressure/Vacuum, Solid State	ea,	175.45	80,43
FRU-8516-097	Guard Electrode Block Assy.,.	ea.	146.25	32.94
FRU-8516-115	Nut, Retainer Needle, Excell Series Pkg of 5	ea.	59,90	102.18
FRU-8516-218	Z55 - Metering tubes/keyboard Ctrl XL seles & XL22	ea.	185.79	37.33
FRU-8740-032	Transfer Tube, EXSAM, XL22 (For Dual Core Needle)	ea.	67.88 35.92	19.75
	Rinse Line (Red), EXSAM	ea.		1,154,98
FRU-8808-001	WOC Acquisition Board	ea. ea	2,099.96 667.87	367.33
	Lan-Ethernet, PC104, (Network Adapter Card)	ea.	377.41	207.58
	Reagent Detector Board	ea. ea	496.38	273.01
FRU-8808-006	Extension/PMT, Pre-AMP board	ea.	1,037.52	570.64
FRU-8808-007	Detector Array, Pre-AMP Board	ea.	1,007.02	070.04

MAR PBK

EDI LARDA-OOR	Sequencer/ Impedance Amp Board (2.2.2 Firmware)	ea.	. 2,808.74	1,544.81
FRI L8808-009	Sequencer Interface Board	ea.	876.98	482.34
FRI L8808-010	Pump / Dilutor Cont. Board (2.2.2 Firmware)	ea.	1,248.50	686.68
FRU-8808-011	Valve Driver Board #1, Front Panel	ea.	. 337,10	185.40
FRU-8808-012	Wash Block / Slide Valve Controller Board	ea.	839.60	461.78
EDIT-8808-014	Laser Temp Sensor Board, Fan Assy, XL22	ea.	258.17	141.99
	EX-Flo Reservoir Assy Excell22	ea.	458.59	252.22
	Exzyme Reservoir Assy Excell22	ea.	459.91	252.95
	EX-Iso Reservoir Assy Excell22	ea.	330.77	181.92
	Slide Valve, Rear Pad Excell22	ea.	1,888.15	1,038.48
	Slide Valve, Front Pad, Excell22	ea.	2,320.29	1,276.16
	Rinse Block Excell22	ea.	159.06	87,48
FRU-0000-025	Slide Valve Bushing w / Drive Shaft and Gear	ea.	466.62	256.64
FRU-0000-020	Slide Valve Motor w/ Goor, Excello?	ea.	839.30	461.62
	Slide Valve Motor w/ Gear, Excell22	ea.	332.04	182.62
	0.2 Micron Filter Assy, Excell22 (Diluent)	ea.	907.28	499,00
	Rinse Block Motor Assy	ea.	183.65	101.00.
	High Vac / Waste Reservoir	ea.	258.12	141.96
	Low Vac Reservoir	ea.	349.09	192.00
	WOC Mixing Motor Assy	ea.	349.09	192.00
	RBC Mixing Motor Assy	ea.	406.62	223.64
	WIC Cuvette Assy		1,451.67	798,42
	WOC Cuvette Assy	ea.	1,004.19	552.30
	Pre-Mix Cuvette Assy	ea.	•	407.62
FRU-8808-039	RBC Cuvette Assy w / Silencer	ea.	741.13	174.75
FRU-8808-040	Linear Actuator 12VDC WOC Injector	ea.	317.74 326,98	179.84
	Linear Actuator 12VDC, 0.001 STP (Sample Aspirator)	ea.		
	Barrier Filter Assy, Excell22	ea.	81.40	44.77
	Dilutor O-ring Kit Excell22	ea.	65,78	36,18
FRU-8808-044	Dilutor Motor, Excell22	ea.	498.25	274.03
FRU-8808-045	Vacuum Pump, Excell22	ea.	821.92	
FRU-8808-046	Pressure Pump, Excell22	ea.	1,148.35	631.59
FRU-8808-047	Laser Assy, Excell 22	ea.	1,365.08	750,80
FRU-8808-049	WOC Tubing Kit Upgrade	ea.	65.23	35.88
FRU-8808-051	WOC Flow Cell Adjustment Tool	ea,	49.50	27.23
FRU-8808-053	WIC Cuvette Assy	ea.	1,709.29	940.11
	UPS 400 VA 230 VAC, International	ea.	3,043.15	1,673.73
FRU-8808-056	UPS 400VA 110VAC, Domestic	ea.	2,607.55	1,434,15
. FRU-8808-057	PMT Assy	ea.	3,242.31	1,783.27
FRU-8808-058	Power Supply Assy	ea.	1,582.13	870.17
FRU-8808-059	Power Supply 5V / 50W	ea.	323.51	177.93
FRU-8808-060	Power Supply 12V / 10W	ea.	511.34	281,23
FRU-8808-061	Diluter/Aspirator/ Injector assy. W Diluter/pump controller	ea.	7,246.03	3,985.32
	Coax Cable, Optics	· ea.	45,60	25.08
FRU-8808-064	I2C Network / Communication Board	ea.	202,18	111.20
FRU-8808-065	Microcontroller, SV / WB, U-5	ea.	43,62	23.99
FRU-8808-067	Dilutor Block and Drive Assy	ea.	3,059.93	1,682.96
FRU-8808-068	Filter Assy, .2 Micron (new - sheath)	ea.	307,67	169.22
FRU-8808-069	Sheath Filter & Valve Upgrade	ea.	549.84	302.41
FRU-8808-070	Cooling Fan Retrofit Kit Excell 22	ea.	745.25	409.89
FRU-8808-072	Flow Cell Assy w / Injector 2 ports	ea.	2,254.84	1,240.16
	Optic Head Assy (Current rev.)	ea.	10,945.28	6,019.90
FRU-8808-074	Flow Cell Injector 2 ports (not for old flow cell)	ea.	179.74	98,86
FRU-8808-075	Start switch W leads & Microswitch with arm	ea.	96.03	52.82
	Injector Barb fittings connectors(5 /pkg)	ea.	71.94	39.57
	Optic head power cable	ea.	106.98	58.84
	V37 adapter block	ea,	197.89	108.84
	Tube clamps & hose clamps pkg of 10 ea	ea.	456.67	251.17
	Fan with wiring	ea.	95.92	52.76
FRU-8808-082	Float switch waste sensor	ea.	454.96	250,23
	Excell 22 Cleaning line .	ea,	102,36	56.30

MR BR

ED11 0000 004	Fibernat Cable, Shiolded	ea.	75.19	41.35
	Ethernet Cable, Shielded V36 adapter block for SSD	ea.	182.55	100.40
	Retrofit Kit, Ex-Sam XL 22	ea,	94,00	51.70
EDIT 8808"100	Bar Code Reader XL 22 (Keyboard Wedge)	ea.	722.92	397.61
	Opticon Barcode Reader, XL22	ea.	722.92	397.61
	Preventative Maintenance Kit, XL22	ea.	2,747.53	1,511.14
	Pump / Dilutor Cont. Board for UI before 2.2.2	ea.	1,303.28	716.80
FPI L8808-117	Sequencer/ Impedance Amp Board before 2.2.2	ea.	2,852.08	1,568.64
	Disk on Chip - 2.2.2 UI	ea.	521,29	286.71
	Disk on Chip - prior 2.2.2 UI	ea,	396.00	217.80
FRI I-8808-120	386SX CPU - PC 104 W disk on chip -rev 2.2.2	ea.	1,854.88	1,020.18
	Front Cover, XL22	ea.	813.51 ·	447.43
FRU-8808-122	386SX CPU - PC 104 W disk on chip - prior rev 2.2.2	ea.	1,673.87	920.63
FRU-8808-123	Programmed Flash, XL 22 - V 2.2.2 (Z53 & Z54)	ea.	238.21	131.01
FRU-8808-124	Programmed Flash, XL 22 - V 3.0.0 (Z53 & Z54)	ea.	174.90	96.20
	Sequencer/ Impedance Amp Board V 3.0.0	ea.	2,979.24	1,638,58
FRU-8808-126	PC104 DISK-ON-A-CHIP (rev 19)	ea.	423.06	232.68
	.SX CPU, PC104, W OPTC20	ea.	1,772.27	974.75
	Switch, Microswitch w / Arm	ea,	45.00	24.75
	Sensor, Pressure 14.5 PSI	ea.	57.75	31.76
FRU-8808-130	Install Cables, RJ45 & Parallel Printer	ea.	23.11	12.71
FRU-8808-131	Cable Assy, I2C, Shielded, 60" (XL 22 Post-date 4/01)	ea.	39,33	21.63
FRU-8808-132	Programmed Eprom, WB/Slide Valve, XL22 (Z-1)	ea.	144.38	79.41
	Programmed Eprom, Dilutor Controller, (Z-4)	ea.	153.12	84.22
	Programmed EPLD, Excell22 Add Dec (U11)	ea.	154.17	84.79
	Piston, Aspiration, XL22	ea.	72.30	39.76
FRU-8808-136	Piston, Diluent, XL22	ea.	40.41	22.23
FRU-8808-137	Piston, Injector, XL22	ea.	72.30	39.76
FRU-8808-138	Piston, Lyse, XL22	ea.	30.19	16,60
	Piston, Sheath, XL22	ea.	35.21	19.37
FRU-8808-202	User Interface V 2.2.2 upgrade kit - XL22 with SP1	ea.	144.21	79.32
FRU-8808-302	Service CD Rev. Win 2000 service packs (V 2.2.2)	ea,	49.78	27,38
FRU-9000-001	Vacuum/Press. Gauge	ea.	1,769.63	973.29
	Nut Driver 1/4"	ea.	37.81	20.80
FRU-9000-003	Nut Driver 11/32"	ea,	40.84	22.46 20.80
	U.S. Standard Ball Allen Wrench Set	ea.	37.81	176.36
	Digital Multi-Meter	ea,	320.65	14.14
	Test Lead Black	ea.	25.71 25.71	14.14
	Test Lead Red	ea.	139.15	76.53
	Flat Blade and Phillips Screw Driver Set	ea.	72,60	39:93
	Needle Nose Pliers	ea.	63.53	34,94
	Diagonal Cutting Pliers	ea. ea.	19.66	10.81
	Precision Knife	ea.	42.35	23.29
	E-Prom Extractor	ea.	30.25	16.64
	Curved 6" Hemostats	ea.	13.61	7.49
	Precision Knife Replacement Blades 3/8" Open/Box End Wrench	ea.	29.40	16.17
	Standard Hardware Kit	ea.	214.17	117.79
	Hydraulic Fittings Kit	ea.	330.99	182.04
	US Std Punch Set	ea.	170.91	94.00
4205-A	Particles, 5.01	ea.	1,633.50	898,43
4207-A	Particles, 6.992	ea.	. 1,633.50	898,43
DC-111	Dow Corning 111 Compound	ea.	48.58	26,72
M-XL22	Manual, Operator, Excell22	ea.	125.00	68.75
M-XL22-S	Manual, Service , Excell 22 (printed copy)	ea.	125.00	68.75
MIXL22	Manual, Operator, Excell22, Infolab	ea.	250.00	137.50
R-001L	Lubricant Slide	ea.	63.69	35.03
R-005C	Light Pipe Cleaner	ea,	121,99	67.09
R-005L	Lubriplate	ea,	17.71	. 9.74
S-0002	Waste Container	ea.	15.00	8.25

HUR BK

Annex 6 Warranty, Technical Support & Training

In addition to the terms and conditions included in Article 3 of this Agreement, it is agreed that:

- If a DREW platform that is under warranty cannot be repaired by POINTCARE, POINTCARE may send such platform to DREW's manufacturing facility for diagnosis and possible repair. POINTCARE will assume full responsibility for all costs associated with the transport of the platform to and from DREW'S manufacturing facility, including but not limited to shipping and insurance charges.
- In the event that DREW HTw platforms sold to POINTCARE incur a material
 manufacturing defect that is epidemic in nature, DREW agrees to bear the
 commercially reasonable and documented incremental costs of service
 incurred by POINTCARE to correct the malfunction.
- If POINTCARE experiences an "out of the box" malfunction of a DREW HTw platform, DREW and POINTCARE's field maintenance personnel shall work cooperatively to ascertain the nature of the problem and the best course of action to promptly resolve the problem.
- Drew agrees to provide complementary initial training to a mutually agreed upon number of POINTCARE's designated technicians and distributors relative to the repair and maintenance of the HTw diagnostic instrumentation platforms. The training will take place at a DREW manufacturing facility. POINTCARE shall bear responsibility for the travel, meals, lodging and other costs incurred by its personnel and agents. Said training will be conducted at as mutually agreed upon during the duration of this Agreement.
- POINTCARE agrees to provide complementary initial training to a mutually agreed upon number of DREW's designated technicians and distributors relative to the use of POINTCARE'S NP instrumentation platform and its CD4 Lymphocyte Enumeration Assay kits at a location to be determined. DREW

MA PR

- shall bear responsibility for the travel, meals, lodging and other costs incurred by its personnel and agents.
- POINTCARE agrees that it shall bear sole responsibility for providing its customers, distributors and other end-users with installation, service and maintenance of the HTw diagnostic instrumentation platforms and that it shall provide all "first" and "second" level support to its customers, distributors and other end-users. First level support is defined as hotline support by either a POINTCARE distributor or POINTCARE directly, during which assistance is provided to the customer in diagnosing the problem in order to troubleshoot large component failures. Second level support is defined as either direct field service repair or delivery of a loaner while the unit is taken back to base for repair. A trained technician would be required to troubleshoot and repair the system in second level support. During the time that this Agreement remains in effect, DREW shall agree to provide "third level" support to POINTCARE, assisting POINTCARE in those few situations where POINTCARE is unable to satisfactorily resolve an issue after utilizing its existing resources. Such support shall be provided by DREW to POINTCARE via telephone or electronic transmission at DREW'S reasonable and customary charge for such service. If a DREW support specialist is requested to provide field support, POINTCARE agrees to pay all costs associated with DREW'S effort to satisfy its request.

MA BK